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THE ROLE OF USE-RELATED INFORMATION IN PESTICIDE RISK ASSESSMENT AND RISK MANAGEMENT

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I. Introduction

EPA's Office of Pesticide Programs (OPP) regulates pesticides to ensure that their use does not pose unreasonable risks to human health or the environment and that pesticide residues in food are safe. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that EPA consider the risks and benefits of pesticide use in making its regulatory decisions. The risk/benefit standard of FIFRA was modified by the 1996 Food Quality Protection Act (FQPA), which amended both FIFRA and the Federal Food, Drug and Cosmetics Act (FFDCA). How pesticides are actually used to control pests is information the EPA must continually pursue to support a number of regulatory activities such as reduced risk determinations, conditional registrations, impact analyses, emergency exemptions (FIFRA, section 18), special reviews, reregistration, tolerance reassessment, and many other activities. In order to make these regulatory decisions under FIFRA and FFDCA, as amended by FQPA, EPA utilizes a wide array of pesticide use-related data pertaining to both agricultural and non-agricultural pest management settings.

The Office of Pesticide Programs is made up of several divisions, each of which has a function and an area of expertise applicable to the regulation of pesticides, and all of whom rely on use-related data in some capacity. The Health Effects Division (HED) provides scientific expertise in toxicology, metabolism (animal and plant), and the potential impacts of chemicals on human health. The Environmental Fate and Effects Division (EFED) provides expertise on potential ecological effects and what happens to chemicals in the environment. HED and EFED are the risk assessment divisions, and in evaluating risks posed by pesticides consider both inherent hazard (toxicity) of a pesticide and the potential for exposure. Data on how a pesticide is used are essential to evaluating both exposure and the productive role of pesticides.

For most conventional pesticides, risk management is handled by the Registration Division (RD) and the Special Review and Reregistration Division (SRRD). RD oversees the registration process, including minor use registrations, emergency exemptions, and establishment of tolerances (maximum residues in food and feed), while SRRD oversees reregistration, tolerance reassessment, and special reviews. In order to manage these processes and develop risk management options, RD and SRRD rely on detailed data regarding pesticide use. In contrast to conventional pesticides, biological and antimicrobial pesticides are handled somewhat differently in that risk assessment and risk management activities are both conducted by single divisions, the Biopesticides and Pollution Prevention Division (BPPD) and the Antimicrobials Division (AD), respectively.

Whether risk assessment and risk management are handled in separate divisions, or by a single division, across all these activities EPA employs a wide range of analytical tools in assessing the risks of pesticides and in making risk management (regulatory) decisions. These tools depend on a variety of use-related information, such as how each pesticide is applied, where and when it is used, how much is actually used, and what it controls. Questions of how pesticides are used and how they work are the domain of the Biological and Economic Analysis Division (BEAD). BEAD is responsible for assembling, analyzing, and evaluating use-related data and providing expert opinion to pesticide program risk assessment and risk management divisions.

The purpose of this paper is to summarize the types of use-related data used by EPA in pesticide risk assessment and risk management, where the data come from, and how the Agency employs these data. (Note: use-related data at EPA have historically been separated into two categories, "use" and "usage," a sometimes confusing distinction that this paper avoids.) The paper is organized into seven sections. This Introduction is followed by two sections that address types and sources of pesticide use data and methods for evaluating and organizing pesticide use data. Sections four and five describe the role of use-related data in human health risk assessments, including drinking water, and ecological risk assessments. Section six summarizes the role of use-related information in risk management decisions. The paper concludes with a short section on future steps for improving both the quality and quantity of pesticide use data, as well as strengthening the analytical approaches for using such information at EPA.

II. Use-Related Information

Use-related data are needed by EPA to carry out its regulatory role in two general areas: risk assessment and risk management. Another application for use-related data is to develop a baseline that details current use patterns for a particular chemical (or class of chemicals) so the Agency can estimate changes in these patterns and the potential impacts associated with regulatory actions. While specific informational needs differ for each type of analysis (which will be covered in later sections) depending on geographic regions concerned and the diversity of crops and pest management options, all analyses need answers to the same basic question: **"How is a given pesticide used?"** Moreover, the level of effort needed to accurately assess a chemical's use pattern often depends on the extent of the regulatory options being considered. For example, as risk for a given pesticide increases, analytical procedures need more detailed use-related data in order to identify and understand the underlying factors that contribute to risk. In the case where regulatory action affecting the continuation of a use is being considered, the level of effort is quite different from the evaluation of a risk management option that would change only incrementally the way a product is used.

Driven by these data needs, the Agency expends substantial effort to collect, analyze, and summarize different types of data. In some cases, the regulatory analysis requires *qualitative* information such as: what is being treated (crops, animals, equipment, premises), why it is being treated (what pests are being controlled), how the pesticide is applied (application equipment, safety precautions, application limitations), and when the pesticide is used (time of year, the growth period of the crop). In other cases, *quantitative* information is needed including: percent of the crop area treated with the pesticide, rates of application (e.g., pounds of active ingredient per area of application), number of applications per season or year, and total pounds of active ingredient per year applied on a site. Use-related information comes from a wide variety of sources which may include pesticide product labels, state and federal agencies, industry and trade associations, registrants, academic literature, and proprietary data bases developed by market-research firms. Data can also be collected in a variety of ways. Among them are producer and end-user surveys or censuses, expert judgement or industry surveys, and laboratory or field-based testing of pesticides.

EPA uses these different types of data at different times, and utilizes a variety of resources to collect them. The following section describes details of specific types of pesticide use-related data that are collected, methods for collecting data, and major sources of these data.

A. Types of Use

Use-related data fall into four general categories: extent of use, typical use practices, pesticide profile, and role in pest and site management. These categories are delineated as follows:

1. Extent of use – *Site* describes where, specifically, pests are being controlled with pesticides. In agriculture, a site refers to a specific crop, livestock, storage facility, or greenhouse plants. In non-agricultural settings, a site can refer to such things as residential buildings or schools (in termite control), laboratory benches (for bacterial disinfectants), telephone poles (for wood-rot control), or drainage ditches (for mosquito abatement – a public health use). *Percent of crop treated* (% CT) is used for agricultural sites and refers to the proportion of planted area of a crop in which a pesticide has been used one or more times. In non-agricultural sites, percent treated refers to the proportion of units treated (e.g., percent of telephone poles). Increasing the number of pesticide applications on a treated area does not increase the percent of crop treated. In order to calculate percent of crop treated, it is necessary to have a value for total planted area (acres) and total pesticide treated area (acres). *Total pounds of active ingredient* (a.i.) used is a measure of the amount of pesticidally active ingredient. *Formulation* describes the "recipe" for a pesticide product, how much of it is the pesticidally active ingredient and how much consists of other ingredients (e.g., water, oil, adjuvants, surfactants). While the Agency also considers the *formulation* in assessing the extent of use, it is primarily interested in the active ingredient.

2. Typical use practices for agricultural products – *Application rate* is the amount of pesticide used on a crop (or other unit) per treatment. It is usually measured as ounces or pounds of active ingredient per acre per treatment (oz. or lbs. a.i./acre/treatment). In cases where the unit of treatment is not a land area, but some other unit, application rate may be expressed as pounds of active ingredient per site-unit (e.g., oz. a.i./cow in the case of ear tags for fly-control in cattle). *Frequency* is the number of times a pesticide is applied during a specific period of time. In the case of perennial crops like orchards, the time period may be a crop year. In the case of non-perennial crops such as carrots, the time period is usually a growing season of several months. *Pre-harvest interval* (PHI) is the period of time between the day of the last pesticide application and day of harvest. For example, if the last application of a pesticide occurred 14 days before a crop was harvested, the PHI would be 14 days. There are also pre-grazing and pre-slaughter intervals for livestock. *Application method* describes both the equipment used and how pesticides are handled in the application process, and may be important in cases where occupational or environmental exposure figure prominently in risk assessments, or when risk management requires specialized equipment.

3. Pesticide profile – This type of use-related data encompasses the attributes of a pesticide that determine its place in a pest management system and influence the choice of alternatives. *Target pests* are the specific pests controlled with a given pesticide. For example, termites in wood structures would be a target pest for a termiticide. *Efficacy* is a measure of how well a pesticide works in controlling a given pest. *Period of residual effectiveness* describes how long a pesticide application works in controlling the target pest. *Effect on beneficial organisms* is important to know in cases when a pesticide may influence naturally occurring organisms that help control pests or have other important characteristics (e.g., honey bees that pollinate crops, ladybugs that eat aphids, mites that eat pest eggs). A related concept is s*econdary pest outbreak*, which may occur when specific pest control measures lead to re-emergence of a relatively minor pest. Secondary outbreaks may occur when populations of beneficial organisms are depleted or alternative chemicals are less effective in controlling previously minor pests. *Phytotoxicity* is the degree to which a pesticide, through direct pesticide/plant interaction, impedes the growth of plants – often a concern for crops grown on land adjacent to the treated site. A related concept is effect on commodity quality, where crop growth may not be impeded, but product quality (and hence value) may decline (e.g., russeting on the surface of an apple). *Route of exposure* is the means by which a pesticide comes into contact with a pest. For insecticides, examples of routes of exposure are contact absorption, inhalation, and ingestion as a stomach poison. *Mode of action* is the mechanism through which the pesticide controls pests. One example of mode of action for organophosphate and carbamate insecticides is acetylcholinesterase inhibition.

4. Role in pest and site management – Other types of use-related information must be considered in order to assess the impacts of possible regulatory actions, such as modifying current use patterns for a pesticide or prohibiting its use, making an alternative pest control method necessary. Important information for making such assessments can be gleaned from knowledge of how commodities are managed and can provide insight about which factors drive the choice of pest control methods. The following factors are examples of this type of data. *Pregrazing intervals and feeding restrictions* are important in cases where pesticide residues may be found on crops fed to livestock. *Appropriate treatment window* indicates when, during a crop's growth cycle, pest control is needed and could be effective to reduce crop losses. *Appropriate application location* describes where, on a site, pesticide applications are most effective. When crops are concerned, location may be foliar or soil. Another example of location may be air-fogging, cracks and crevices, or internal wall spaces in buildings for roach control. *Compatibility with other pesticides* may be important in cases when more than one pesticide is used on a site within a specific time period. *Geographical differences in use and effectiveness* may be crucial in determining where risk management alternatives could work. Knowledge of *crop rotations* may help to determine which sequences of crops are feasible (and legal) for different pest control regimes. *Current market share and prices* of pesticides and availability of alternative control methods are critical to the pest control decisions of individual farmers, and are integral to the risk management process.

B. How Data Are Collected and Analyzed

The types of use-related data described above vary in their specificity, as well as the degree to which they may be quantified. As such, no single data collection method can be used to develop data bases for these heterogeneous data types. Therefore, data collected by the EPA are based on a number of collection and analytical methods.

1. Pesticide labels – Pesticide product labels are a baseline source of use-related information. Because it is unlawful to use a pesticide in a manner inconsistent with its labeling, pesticide labels establish the range of legal use patterns for a chemical including: sites that may be treated (agricultural and non-agricultural), maximum allowable application rates, application methods (type, timing, and equipment), limitations on the use of pesticides (e.g., minimum preharvest and/or reentry intervals), and other information that is crucial in determining legal use patterns. Some product labels include a list of pests controlled although, in general, one may apply pesticides to control a pest not listed on the label as long as that use is not prohibited and is not inconsistent with other label restrictions (FIFRA section 2 (ee) (2)). Most of the key information from approved pesticide product labels is contained in the *Label Use Information System (LUIS)*, an EPA data base of use patterns describing the legal limits of use for currently registered pesticide products.

The major advantage of label information is that it describes allowable uses for a pesticide product, and makes a good starting point for studies of pesticide use in the reregistration process. The shortcoming of product labels is that they do not provide information on how these products are actually being used, which is why the EPA also relies on a number of other data sources.

2. Survey and census data – Surveys are primary sources of detailed, quantitative information reflecting actual product use-patterns of pesticide users. In many cases, surveys collect information from a statistically representative sample of pesticide users, and then use information about the whole community of pesticide users to infer total use patterns. Most commonly, surveys are done at the state level, and can then be aggregated to the national level. Occasionally, however, surveys are done at the regional level including several states. In rare cases (California is the only current example), census data are available which represent a survey of all agricultural pesticide users in a given area or state. Some surveys are performed regularly (annually or bi-annually) and are available for a number of years on numerous sites in numerous locations. Other surveys are conducted for specific industries or user groups and may be available only for a single, fixed period of time and location.

Survey and census data have several major advantages and some disadvantages. Surveys and censuses collect detailed, quantitative information – representative of the whole population of pesticide users – which can be used in quantitative analytical tools. By collecting data directly from users, these data collection methods may also generate the most accurate data reflecting actual pesticide use. Moreover, in many cases, one can also obtain the range within which estimates are statistically valid (e.g., confidence intervals). Their main disadvantage is that surveys and censuses can be quite costly. Not only are they costly to produce, but they also require time and effort from people who participate as survey respondents. Moreover, there are few reliable ways to assure the reliability of a user's response, short of detailed interviews with respondents, so the most reliable and extensive surveys are generally the most costly. Lastly, given the wide range of sites – both agricultural and non-agricultural – in which pesticides are used, the number of surveys is relatively limited and tends to reflect data from larger and/or better-organized user groups.

3. Efficacy testing – Efficacy testing measures how well a pesticide controls pests and involves applying pesticides to crops infested with target pest(s) of interest. Pest populations are monitored before application and at several intervals after application. Pesticides can then be rated based upon the extent to which they control target pests over time. In some cases, yields are also measured at the end of the season to determine the relationships among pesticides, pest populations, yields, and quality. The strength of efficacy testing is in providing information on the effectiveness of a given pesticide and its potential alternatives in comparative test plots. One disadvantage is that a single field test rarely evaluates all alternatives at the same time, so comparisons between pesticides may be indirect in that they compare tests done at different locations at different times. Moreover, sets of field tests across locations may not portray regional differences in efficacy that arise from different ecological conditions or pest populations. These regional differences are evident from cases where efficacy tests are conducted over time in different locations, and clear differences in regional trends appear.

4. Expert judgment/industry study – A wide range of crop and pest management reports are regularly generated from selective interviews with farmers, pest control advisors, commodity groups, Agricultural Extension Service personnel, and industry experts. This type of report concerning pesticide use provides the Agency with critical "real world" information regarding pest problems and pest control issues including crop production practices, pest biology, integrated pest management, and pesticide resistance management programs. In addition to printed sources available to the Agency, EPA staff may contact crop and pest management experts at the state and field level to obtain their views on crop and pest management practices.

The major advantages of this type of data are that they are often based on years of experience of the experts involved. Experts can also provide insight into the idiosyncracies of certain pest control situations where complex relationships might not be adequately described by other sources of data. Furthermore, expert judgment data are usually relatively inexpensive to collect. The major disadvantage of expert judgments or industry studies is that they are not always systematic and may reflect the particular sensibilities (e.g., biases or limitations of experience) of those providing the information. Therefore, this type of report usually requires validation from separate sources and more in-depth analysis. At the same time, expert judgment may be the only reliable data available on use patterns in many minor crops and non-agricultural commodities and sites.

Table 1. Methods for Collecting Use-related Data

Method of Collection	Cost of Collection	Reliability
PESTICIDE LABEL/LUIS	Relatively inexpensive to extract information from existing labels.	Very reliable in documenting label information. Provides little information on how pesticides are actually used.
SURVEY	Can be costly, especially surveys with greater depth, breath, and reliability checks.	Can be very reliable. Useful for projections beyond the limited survey sample when attention is paid to sampling method, sample size, response rates, and reliability procedures.
CENSUS	Can be extremely costly, especially as depth, breadth, and reliability checking increases.	When properly designed and executed, a census should generate the most reliable information.
EXPERT JUDGMENT	Relatively inexpensive in general.	Reliability varies greatly depending on the experience and biases of those whose opinions and estimates are included in the study.

C. Major Sources of Data

EPA pesticide use-related data come from a variety of sources for both agricultural and non-agricultural pesticide uses. Data sources vary greatly in the type of information gathered, frequency of data collection, method of data collection, and format of the data provided (e.g., paper copy or electronic data). Sources of use-related data fall into five general categories: (1) other government entities that produce pesticide-use data; (2) data submitted by registrants, user organizations and other interested parties; (3) proprietary data purchased from vendors whose business is to obtain pesticide-use data; (4) academic press; and (5) miscellaneous Agency contracts and sources. Each category is described below.

1. Other government agencies – EPA has obtained pesticide-use data from the ***USDA National Agricultural Statistics Service*** *(NASS)* for many years. In 1990, NASS expanded its collection of pesticide-use data to fulfill its mandates under the 1990 Farm Bill. Data collection mandates have continued under the 1996 Food Quality Protection Act. NASS conducts farmer surveys to collect pesticide-use data on major field (e.g., corn, cotton, soybean), vegetable, and fruit crops in states that account for the bulk of production of these crops (details can be found at the NASS website: **http://www.nass.usda.gov**). Annual surveys always include row crops and alternate between sets of vegetable and fruit crops. Data include acreage grown, acreage treated, number of pesticide applications, application rates, and total amount of pesticide used for three types of pesticides – insecticides, fungicides, and herbicides. Even though NASS has collected data for all pesticide use, reporting is only done for crop/pesticide combinations that NASS considers statistically valid. For example, NASS may collect data for a particular chemical on a particular crop, and report the existence of the data, but not report estimates of use. In the past, EPA has obtained and used publicly available data from NASS. More recently, however, NASS has agreed to provide EPA with additional information from its surveys – information not generally available to the public – which can assist in the preparation of refined risk assessments.

USDA also provides EPA with data from several other sources of use information, using a variety of data collection methods. USDA crop profiles provide information in narrative format about crop production, cultural practices, and pesticide use. They are generated by State Liaison Representatives and other entities through research on crop production and crop protection experts in their respective states [**http://ipmwww.ncsu.edu/opmppiap**]. These profiles are generally based on a combination of expert opinion and summaries of secondary data sources.

For many years, EPA has also obtained publications from the USDA ***National Agricultural Pesticide Impact Assessment Program*** *(NAPIAP)*. NAPIAP reports usually feature either primary uses for a specific chemical or comprehensive pest control information for a specific crop. In some cases NAPIAP reports rely on expert judgment and recapitulations of already-published studies. In other cases, the reports provide pesticide use data from original surveys, giving applications rates, numbers of applications, and total pesticide use for a given crop to control specific pests. EPA also relies on the USDA **Census of Agriculture** for its uniform, comprehensive data on agricultural production and operator characteristics in each county and state, as well as the U.S. as a whole. Other data sources include USDA scientists who do laboratory and field research, and specialists in the Animal and Plant Health Inspection Service (APHIS) involved in quarantine programs.

EPA also works with the ***California Department of Pesticide Regulation*** *(CDPR)*, which conducts a pesticide-use census in the state. California law requires agricultural producers in the state to report every instance in which agricultural pesticides are used. Users of agricultural pesticides submit monthly reports to county agriculture officials. Data include pesticide name and formulation, the crop on which a pesticide was used, amount of use, and area covered. Because target pests are not included in the census of pesticide use, EPA scientists frequently contact California scientists to determine the significance of using specific chemicals. Over time, CDPR has invested substantial resources to provide quality use-related data to the public. EPA has CDPR census data for three years (1993 - 1995), which are available publicly and in a form usable by EPA. EPA is currently working with CDPR to expedite EPA's acquisition of the most recent years of data (1996 - 1997), and to gain greater access to additional data prior to their release to the public.

Most state departments of agriculture publish pest control, crop, and livestock management recommendations for important agricultural commodities in the state. These documents are generally called ***State Recommendations***. Sometimes pest control recommendations appear in individual volumes dedicated to pest control issues, and in other cases, recommendations are included in state crop production guides. Recommendations are generated by personnel in the Agricultural Extension Service, many of whom are scientists affiliated with public universities. These scientists develop recommendations using state surveys of agriculture, agronomic studies and experiments, specific pest control studies and experiments, label information, and field experience. For major crops in some states, recommendation guides are updated and reissued on a regular basis.

Publications of State Recommendations are valuable because they describe the views of the agricultural science community in each state about important issues such as which pesticide products are most likely to work against the pests in their area, how often they may need to be used, and at what rates. They also provide information about specific agricultural and non-agricultural pest management problems in a given state. While these publications are usually examples of expert judgement, they are often based on results from surveys and field studies.

Many states provide a variety of other information resources, using different combinations of data collection methods. In addition to State Recommendations, many state departments of agriculture have conducted surveys of pest management for specific crop or commodity/pest combinations. These reports may contain important pest management information and pesticide use-related data. In many cases there are few, if any, written documents on particular minor uses or occasionally devastating pests. Lacking published data, BEAD scientists make inquiries of research and extension scientists to elicit expert judgment.

Lastly, individual states or tribes often submit data in support of emergency exemption (FIFRA Section 18) requests for use of a particular chemical on a particular crop in their state. These data provide information on pest emergencies and characterize the availability of effective pest control methods. As a condition of approval of an emergency exemption, states are sometimes required to keep records of use and the results of the use.

2. Registrants, users, and grower groups – EPA also obtains use-related information from a variety of interested parties. For example, registrants may submit data in support of a new use or risk mitigation, or in the form of a registrant-sponsored risk or performance study. Use-related data vary and may include efficacy information, suggested and actual application rates, methods of application, and timing of application. In some cases registrants submit data on their own initiative to expedite the review or registration process. In other cases, the Agency requires that certain studies be conducted by registrants.

Pesticide user groups, agricultural producer groups, food processors, and many commodity and trade organizations are also important sources of use-related data. In a number of cases, agricultural producer groups have helped the Agency acquire data by conducting surveys of their members regarding the extent of pesticide use and typical use practices for particular crops. Such reports are valuable because they often provide detailed quantitative data and qualitative data about pest management for a use area or crop, and offer insight into the decision-making process of pesticide users. In many cases the reports are publicly available, but in others the reports may be provided to EPA as confidential business information. Because some industry and trade groups may be concerned about releasing data that could be used in regulatory actions against themselves, EPA is working with these groups to reduce confidentiality concerns. In one case, EPA and an industry group is using an independent intermediary to summarize raw data and remove user-specific identifiers that could cause such confidentiality concerns.

3. Proprietary sources – EPA has contracted with firms in the business of collecting and selling pesticide use-related data that assist EPA in understanding the way pesticides are used, as well as providing insight into pesticide markets. Data purchased from private firms must be bought under proprietary agreements. Such data are not available to those who have not entered into agreements with the provider.

The data from pesticide-use data collection firms vary in terms of what data they collect and the number of respondents in their surveys. EPA's main proprietary data for agriculture are available for major crops and commodities and include: product or brand names, target pests, producer of the pesticide, the crop to which the pesticide is to be applied, how much is applied in each state or county, information about application to transgenic plants and seed types, percent of crop treated, numbers of applications, application rates, total amount applied, and order of pesticide applications (which specific pesticides are applied in particular sequences). These data are collected for a large range of row, vegetable, and fruit crops in the continental U.S. and include insecticides, fungicides, herbicides, nematicides, and growth regulators used by producers. Some surveys of specialty/minor crops cover a smaller range of crops and pesticides and may cover only a portion of the continental U.S. In most cases, the data collection method is an annual user survey.

EPA also contracts with firms that specialize in collecting non-agricultural use data, but this type of information is more limited. For example, from time to time, private research firms have published surveys and studies that contain use-related information on public health, turf, ornamental plants, urban pests, forestry, rights-of-way, aquatics, and consumer markets. There is great variability in data collection methods and scope of data, depending on the focus of a particular study. EPA has purchased a number of these publications to supplement its use-related data for non-agricultural sites. Other examples of the types of data and application sites covered by these studies include registrant sales, global non-crop pesticide market data, chemical additives and adjuvants, processed fruits and vegetables, household cleaning products, industrial cleaning products, paints and coatings, professional pest control, and turf, golf courses, and nursery/greenhouse ornamentals. Many of these data bases covering niche uses are only available sporadically, which limits the strength and confidence of analyses. The data bases may also be prohibitively expensive to obtain on a regular basis. They do, however, provide BEAD scientists with indicators that can be used as starting points for soliciting information from scientists and other sources outside EPA.

4. Academic press, journals, and trade publications – A rich source of data regarding the role of pesticides in agricultural and non-agricultural pest management is the academic press. This includes both books and journals in which many pest control studies are published. Depending on the particular publication, the use-related data may cover any of a wide range of topics, from application rates to efficacy, to application methods, and more. Trade publications, including trade journals, can also provide a wealth of data similar to that found in the academic press, although it is not necessarily subject to the same peer review process. In the past, EPA has made extensive use of both academic and trade publications.

5. EPA project/contract surveys – Occasionally, EPA finds a lack of public and proprietary data for an important set of pesticide use sites and if resources are available, commissions a study to fill this gap. In the last decade, the Agency has commissioned studies of pesticide use by certified commercial pesticide applicators to gain an understanding of their pesticide use practices, contracted a home and garden pesticide use survey, and sponsored a study of post-harvest agricultural pesticide use. Such contracts can be quite expensive, but in filling particular gaps in use-related data they can be quite useful. Under constrained budgetary circumstances, the Agency prefers to employ use-related data from sources that already exist rather than generate them using limited Agency resources. But, in some cases – particularly for non-agricultural sites – such projects or contracts may be the most effective way to collect data.

III . How EPA Organizes and Evaluates Pesticide Use Data

The preceding section contains an overview of the types of use-related data EPA collects, how they are collected, and the sources of such data. The raw data cover a wide range of pesticide use issues, and in many cases there is more than one method for collecting a particular type of data and more than one source that provides it. Therefore, once EPA's biological and economic scientists have collected and analyzed all the available raw information about the use of a particular pesticide (within the allotted time frame), the information must be evaluated, organized, and presented to risk assessors and risk managers in an understandable format so they can use it in the decision-making processes. Furthermore, when considering risk management proposals in cases where risk mitigation is warranted, EPA analyzes the potential effects or impacts of different mitigation scenarios, a type of analysis broadly defined as impact analysis. In pursuing quality assurance and control, EPA also often consults with USDA and user groups to review EPA's evaluation and organization of use-related data. This section describes the four primary methods that EPA uses to organize and evaluate pesticide use data: (1) label use profiles, (2) quantitative usage analyses, (3) crop matrices and supplementary use-related information, and (4) impact analyses.

A. Label Use Information System (LUIS) Reports

Pesticide labels provide information that is entered into an electronic data base called the Label Use Information System (LUIS). Label data include product type (e.g., technical grade, manufacturing use, end use), pesticide formulation type (e.g., dust, granular, ready-to-use liquid, pressurized gas), pesticide type (e.g., herbicide, insecticide, disinfectant), use sites, allowable application rates, and how it is applied, such as application method type (e.g., spray-on, broadcast, sprinkle), application timing (e.g., pre-harvest, pre-plant, dormant, etc.) and application method or equipment (e.g., back-pack sprayer, metering pump). Detailed information is extracted from the approved product labels and "input" into the system. It then goes through a rigorous quality control process. Once the data have gone through quality control and validation, a number of specialized reports may be generated by the system. Specific reports are available on request.

The LUIS reports reorganize and standardize label data so staff in the science divisions in EPA's Office of Pesticide Programs can use them for their assessments. One of the LUIS-generated reports is the *Use Profile,* a brief summary of a chemical's label information containing pesticide type, use sites, method of application, and target pests (see Appendix A for a sample LUIS Use Profile). The Use Profile is an integral part of a *Reregistration Eligibility Decision (RED)* document.

B. Quantitative Usage Analysis (QUA)

The *Quantitative Usage Analysis (QUA)* is another tool the Agency uses to summarize use-related data for risk assessment. For a given agricultural chemical, a QUA provides estimates – for each site where the chemical is used – of the following information regarding actual use: acres grown annually, percent of crop or units treated (both average and maximum), total annual use (average and maximum), application rates, number of applications, and states where the pesticide is most used. For non-agricultural sites, data are more limited and the QUA usually lists only the site and the national annual use of the pesticide on that site. Generating a QUA is a procedure involving several steps and this section provides an overview of those steps.

First an analyst generates a list of alternative names for a given chemical and the sites on which it may legally be used. This information is contained in EPA's *Reference Files System (REFS),* a data base of pesticide names, product brands, use sites, target pests, and other similar data.

Using the list of names and sites as input, an EPA analyst then uses an automated program to generate a preliminary QUA. The *Automated Quantitative Usage Analysis (AQUA)* is a computer program that extracts – for a given chemical – quantitative use-related data from EPA's pesticide use data bases. Not all the EPA sources described above provide their data in electronic form, and manually entering all data into electronic format is not feasible for a number of reasons (e.g., volume and heterogeneity of data, differences in definitions across sources, narrative nature of some sources). For crops where many of the use data are not in electronic form, the QUA generated by AQUA is preliminary and must be supplemented manually with data from printed sources.

The AQUA program has evolved since it was first introduced in 1993. EPA is now finishing a revision of the AQUA program that will extract additional data that may be needed for refined risk assessments under FQPA. Details of the AQUA program are currently being summarized and will be available in a technical paper that will be publicly available in the near future. For this paper, a general description of the program output follows.

The AQUA program first standardizes data to generate consistent crop, product, and pesticide identifiers that often vary across different sources. For example, some sources name pesticides by their brand name and others name them by their active ingredient. Then, for agricultural pesticides, the program extracts *state-level estimates* of percent of crop treated, application rates, and number of applications from each source for each year (up to 10 years of data). Estimates from different sources are then averaged *within each state*, with weights used that reflect the size of the survey sample from a given source. Surveys with larger samples in the state are given greater weight since their data cover a larger proportion of actual use within that state. Estimates are then aggregated across states to generate national estimates (for each of several years) of quantitative use-related data. The estimates for the different years are then averaged using larger weights for more recent years, based on the observation that recent years are more representative of current normal use patterns than earlier years. The result is a national estimate of pesticide use for the following parameters:

(a) number of U.S. acres grown
(b) average number of acres treated (weights described above)
(c) average percent of crop treated
(d) average number of pounds of active ingredient (a.i.) applied
(e) average annual application rate: pounds of a.i. applied *per acre per year*
(f) average annual number of pesticide applications
(g) average application rate: pounds of a.i. applied *per acre per application*

In addition to the estimates of weighted averages, the AQUA program also estimates the maximum likely number of acres treated, percent of crop treated, and total pounds of active ingredient. For these use parameters, rather than report the maximum *observed* level in the sample period, the AQUA estimates a *probabilistic (or likely)* maximum. This is done because a particular maximum observed during the survey period may not represent conditions of the worst possible pest infestation that would lead to the maximum likely pesticide use. Because the worst possible pest infestation may not have occurred during a survey period (even a 10 year period), more damaging infestations might occur resulting in higher levels of use than any observed levels.

The likely maximum is calculated using statistical procedures which set usage levels below this maximum approximately 95% of the time. This likely maximum is obtained in three stages:

(1) Estimate a regression of usage versus time to correct for trends over time. A regression is a statistical procedure used to characterize how usage changes over time and the variability in those changes. Correcting for trends over time accounts for variability among time periods, which would inflate the likely maximum in the absence of this correction.

(2) Using the regression results, the procedure calculates an approximate 95% prediction-type interval for the different types of usage. This interval represents additional usage, over and above average usage, that accounts for 95% of the observed usage, and is approximately twice the standard deviation of estimated usage. Adding the interval to the weighted average generates the likely maximum.

(3) In some cases, small numbers of observations generate very large prediction intervals using this procedure. In such cases (currently set at 4 observations for iterative regression methods) a deterministic rule is used to limit the upper bound of the likely maximum, where the likely maximum is calculated as twice the maximum *observed* usage level in the most recent three years for which EPA has data. This expression is also used as an upper bound on the likely maximum calculated using the regression method. In other words, the likely maximum is chosen as the lesser of the following:

i. {weighted average} + 2 {standard dev.}
ii. 2 {weighted average}

When deriving estimates of likely maxima using probabilistic methods, one must address several issues that arise with respect to making statistical inferences with the pesticide data available to EPA. One question that arises is whether each of EPA's pesticide use data sources has a randomly drawn sample. This is important because random sampling from the population of pesticide users assures that the data represent the actual distribution of pesticide use, and that estimates of likely maxima are reasonable. In fact, until 1999, EPA's primary sources of data on pesticide use in agriculture – both public and proprietary – employed sampling methods that can be described as quasi-random (and stratified) sampling. These sources maintain and update lists of farmers and other pesticide users. The lists are categorized according to farm size and location, and then used to identify cooperating pesticide users and gather data. Although sampling from a fixed list – or subset – of pesticide users may not be random in the strictest sense, given the very large size of these lists, the stratification process, and the verification procedures used by large data sources, EPA analysts consider the data to meet randomness criteria for statistical inference.

A second question concerns whether the estimation procedure generates data that are normally distributed. This is important because statistical inference from least squares regressions are often based on the assumption of normally distributed residuals, and this assumption influences the estimate of the 95% prediction interval. With a limited number of observations, one may not be able to verify the normality assumption, which would complicate statistical inference. Therefore, EPA analysts address this issue by using a deterministic, rather than probabilistic, likely maximum where there are few observations (described above). Another strategy is to use iterative regression techniques to construct a distribution of least squares residuals – rather than assume normality – that can be used to estimate the prediction interval used in calculating the likely maximum. Mindful of these issues, EPA analysts try to use statistical methods that are appropriate to the available data in calculating likely maxima.

To reiterate, the QUA contains (continuing from the list above) the estimates of likely maximum for the following:

(h) likely maximum number of acres treated
(i) likely maximum of percent of crop treated
(j) likely maximum number of pounds of a.i. applied

Two enhancements are planned for the upcoming version of the AQUA program, which will assist with the refined risk assessments required by FQPA. The first enhancement will provide regional estimates in addition to the national estimates. The regions will correspond to the four regions – groups of states – used by EPA in conducting dietary risk assessments (Northeast, Midwest, South, West). The second enhancement will provide information about the distribution of application rates and pre-harvest intervals. Distribution refers to the proportions of users applying pesticides at a given rate (or using a given pre-harvest interval), i.e., how many users apply a particular pesticide at 0.1 lbs a.i./acre and how many apply at 0.2 lbs a.i./acre, and so on. As described in later sections of this paper, the Agency will be able to use such data to incorporate greater refinements into risk assessments.

For non-agricultural sites, the AQUA program usually provides only a national level estimate of total use (in pounds of active ingredient). A national-level evaluation is provided because most EPA sources of information about non-agricultural pesticide use do not report much more quantitative data than total amount of use. In cases where use estimates are extracted for more than one year on a given site, a weighted average is calculated giving greater weight to more recent years, as described for estimates of agricultural use.

After the automated program has been run, EPA analysts refine the automated, preliminary QUA. They may revise an estimate when additional data, not available in electronic form, are available and add non-agricultural site information not included in pesticide use data bases. More importantly, analysts also check estimates against other sources – including expert judgement inside and outside EPA – to assure that estimates are consistent with patterns of pesticide use. In some cases, there may be evidence that the pest control landscape is changing rapidly due to such factors as newly introduced pesticides or changing pest populations. When evidence for such changes occurs, but is not reflected in historical use patterns, EPA analysts take this evidence into account in making (or annotating) pesticide use estimates.

Finally, analysts organize final estimates into the QUA format for use by risk assessors and risk managers (see Appendix B for a sample QUA).

C. Summary and Supplemental Use-Related Information

EPA has developed the *Organophosphate (OP) Crop Matrices* to organize the available use-related data for organophosphates on a crop-by-crop basis. These crop matrices provide an evaluation of use-related data based on crop issues, whereas LUIS and QUA methods are organized around particular chemicals. The crop matrix format of the matrices facilitates risk assessment and risk management, and helps to identify areas where more information would be useful. The matrices each contain two sections: a crop summary and a pest summary, and require resource intensive analyses by scientists.

The *crop summary* contains information on where the crop is grown in the U.S. along with which OPs are used on the crop. For each OP, the crop summary includes percent of crop treated (actual average and likely maximum), number of applications (actual average and allowable maximum), application rate (actual average and allowable maximum), and pre-harvest interval (allowable minimum). In addition, the crop summary lists the key crop pests that are the target for the bulk of OP applications and the other targets pests that receive relatively minor amounts of OPs.

The *pest summary* provides additional information on crop pests that are the target of OP use and the alternatives to OPs for controlling each pest. For each pest, the summary lists all the OPs used to control it, the alternative pesticides for that pest in each region, and information about the efficacy (when available) and market share of each OP and alternative pesticide. Additionally, the pest summary lists particular constraints that may be associated with alternatives to the OP insecticides.

Crop matrices are developed using a wide variety of sources. State Recommendations provide information on which pests and control chemicals are associated with a given crop, along with sets of alternative pest management options and the constraints of each. QUAs indicate how much of each pesticide is used on a crop and which are the dominant pesticides. Field tests give data on the efficacy of different controls on various pests. EPA may also use other published reports, or contact pest management experts associated with the crop to complete the profile for a crop matrix. Each matrix is footnoted with the sources for all data used in the analysis. In addition, USDA is cooperating with EPA in the development and review of the OP matrices. EPA has already posted draft OP Matrices for 10 crops to the Internet at **http://www.epa.gov/oppbead1/matrices** . Other matrices will be posted on the web as they become available (see Appendix C for a sample crop matrix). To date, the crop matrix format has not been expanded to non-crop agricultural sites such as livestock or poultry, or to non-agricultural sites in general.

In the case of OP pesticides, EPA has also developed a data base of supplementary data. This data base (formerly referred to as QUA+) contains information from a special project on organophosphates, and involving growers and registrants in an effort by the EPA to acquire background information to supplement QUAs in FQPA decisions. For a specific crop/chemical combination, the data base includes typical application rates, pre-harvest and pre-grazing intervals, application methods and timing during the growth cycle, main target pests, pesticide market share and trends, and potential alternatives to the given pesticide as obtained from the survey. Data are entered in a text format and quantitative data contained in the data base (e.g., application rates) may be difficult to summarize or analyze in other ways.

D. Evaluations of Risk Management and Mitigation Options

In cases where the risk for a given pesticide or set of pesticides exceeds acceptable standards, EPA develops plans to mitigate or manage the risk, when such options are feasible. (Sections IV and V describe how EPA assesses the need for risk mitigation.) As mitigation options are developed, or regulations are promulgated to implement the plans, the Agency conducts analyses to predict the effects of these mitigation options and regulations. The analyses are intended to answer several types of questions including:

- What would a proposed action mean to actual users of pesticides?
- Where is the actual use of pesticides that would be affected by the action?
- How would pesticide users likely respond to the proposed action and what portion of current treatments would be replaced by one or more alternatives?
- What would be the consequences to users with respect to changes in pest management systems, yields/productivity, costs, and income?
- Would impacts on users affect commodity prices locally, regionally, or nationally, and would there be spillover to other commodities or sectors?

In estimating the implications for pesticide users, industries using products made with pesticides, and consumers, two types of detailed analysis are usually made by EPA scientists: a biological and an economic analysis using the full range of data sources and summaries described above. These analyses may cover all use sites and formulated products for which an active ingredient is registered, or some subset of them, depending on the Agency regulatory concern about the chemical. In instances where a chemical poses a critical health risk and has food or crop uses, generally all sites will be included in the analysis. More limited analyses may be needed where risk is traceable to only certain geographic areas, product formulations, application practices, or dosage rates. Analyses are usually planned that cover as much as possible of the actual use of the pesticide causing regulatory concern.

1. Biological impact analysis – The key elements of a biological impact analysis are to identify and characterize the major pests controlled, potential alternatives, comparative performance evaluation and viability of alternatives, potential impacts from changing pest management behavior, potential yield impacts, and geographic distribution of these factors.

Biological scientists identify major target pests controlled by the chemical for which mitigation is necessary. In some cases, limited specificity is needed (such as "broadleaf weeds" rather than particular weed species). In other cases, it is necessary to identify very specific pest species. In addition to identifying the target pests, EPA scientists analyze the geographic distribution of the pests, particular characteristics of the pest population (e.g., pesticide resistance in some areas), and specific ways that pest management is incorporated into the crop or commodity management. For major pests of larger use sites (e.g., bollworm on cotton), data are abundant and readily available. For minor or localized uses, it can be difficult to determine where and why a particular pesticide is needed and the implications of changing its allowable use. As a result, evaluations of regional or minor uses typically rely heavily on contacts with state specialists.

Based on the analysis of target pests, EPA scientists can identify potential alternatives to the chemical under review, and evaluate performance of the chemical compared to the potential alternatives. In some cases, an option would be a simple change in the use pattern for the chemical under review, or a change in cultural practices. In other cases, the option might be a different chemical with different performance ratings. Comparative performance assessments are made on the basis of field tests conducted in university experiments, on cooperating farms or other users of pesticides, and proprietary tests conducted by registrants. A range of other issues need to be considered describing how alternatives may influence the pest and commodity management environment including potential for secondary pest outbreaks, effects on beneficial insects, requirements for specialized equipment, changing pre-harvest or pre-grazing intervals, and more.

In conducting comparative performance analyses for pest control methods, EPA scientists also pay particular attention to how well the different methods work. In the case of non-agricultural sites, such as termite control for buildings or mosquito control for public health, performance may be judged by populations of the pest itself or the damage these pests cause (i.e., ability to spread diseases like malaria or dengue fever). In the case of agricultural commodities, EPA scientists focus on impacts on crop yield and quality. Since quality-grades of processed crops (like spinach) may decline with the presence of pest contamination, pest populations themselves may cause negative impacts even when the commodity itself is unaffected. These yield and quality effects will influence net revenues to pesticide users and will be important in economic analyses. Generally speaking, however, it is difficult to make precise long-term predictions of comparative efficacy and yield or quality changes because of uncertain factors such as weather, evolution of pest populations, and economic conditions that may change the viability of certain alternatives.

2. Economic impact analysis – EPA economists estimate the economic consequences of risk management options and regulatory actions in order to assess potential impacts on pesticide users, intermediate and final consumers of commodities produced using pesticides, and others affected either by pesticides or the results of changing allowable uses. Although allowable risk must conform to the reasonable certainty of no harm standard, there are numerous ways to allocate allowable risk to different uses, and the options for allocating risk need to be assessed. In so doing, Agency economists also estimate how these impacts are distributed across society, in aggregate and per capita. Some factors (e.g., the importance of the subject chemical to resistance management) cannot be quantified. Economic effects are generally estimated for the short-term (1-5 years). Longer term projections are more difficult because of unpredictable changes in pest problems and market shifts, as noted earlier. A number of analytical tools are available to Agency economists, from partial budgets to much more rigorous programming and statistical models. The method chosen for a particular analysis depends on factors such as the level of precision desired and the availability of data to support analytical efforts.

Economic analysis begins with the results from biological impact analyses and quantitative use analyses, and incorporates a wide range of other detailed quantitative economic data. The use of a particular pesticide implies that users consider the pesticide to be the most cost effective option available. After collecting and analyzing detailed price and cost information, EPA economists calculate how the costs of production and pest management will change if other options replace a particular management scheme. In addition to potential changes in costs, estimates are made of changes to revenues, through changes in both the volume and quality of output. Price effects may result from aggregate changes in output levels, and these may need to be considered to estimate net effects on pesticide users. Economic effects for users are site specific and often regional as well.

Economic impacts are also estimated for markets linked to commodities produced using pesticides because shifts in output, production costs, or price for one market often affects other markets. Intermediate food/commodity processors and consumers may experience price, availability, and market substitution effects. For example, in the case of corn production, changes in pest control options could influence the price of corn, which might in turn affect prices for breakfast cereals, soybeans, and meat – markets all linked to corn. Additional factors that may be relevant to the economic analysis include agricultural subsidies, minor crop usage, international trade issues, alternative crops, and other potential market adjustments.

When significant effects occur at the market level, there can be broader effects on society. In other words, reregistration of pesticides may cause a net impact on economic well-being for specific groups in the U.S. economy, and also influence the non-economic well-being of these same groups. Attention is paid to this broader net effect as well as the impacts on identifiable sub-groups such as children and/or nursing mothers.

IV. The Role of Use-Related Data in Human Health Risk Assessment

Use-related data are critically important to the risk assessment process. Specifically, they are used in making decisions concerning the FQPA Safety Factor for infants and children and they are used in all phases of exposure assessment:

- Decisions Regarding the FQPA Safety Factor
- Assessing Dietary Exposure from Food

· Assessing Dietary Exposure from Drinking Water
· Assessing Residential Exposure
· Assessing Occupational Exposure

Except for dietary exposure from drinking water (which is discussed in Part V), this section provides a discussion of how use-related information is used in each of these aspects of risk assessment. Part A provides a brief description on how the Agency conducts human health risk assessment while Part B lists which use-related information, broken down under the categories of "Extent of Use" and Typical Use Practices for Agricultural Products," are used in the various aspects of risk assessment. Finally, Part C provides a summary table showing where use-related information is used in human health risk assessment.

A. A Primer on Risk Assessment

As discussed in Section I of this paper, EPA scientists conduct human health risk assessments to ensure that pesticide use does not pose unreasonable risks to human health and that pesticide residues in food are safe. Three broad categories of human health risk assessment are conducted: dietary, residential, and occupational.

The risk that is posed by a pesticide – be it from exposure to pesticide residues in food, in and around the home, or in an occupational setting – depends on the toxicity of the pesticide and the amount of pesticide to which a person is exposed. That is, to determine whether there is any risk – which can result from exposure that occurs for a short, long, or intermediate duration – one compares the inherent toxicity of the pesticide to the amount of pesticide to which an individual may be exposed during the appropriate time period. The toxicity is expressed as either an acute reference dose (aRfD) or a chronic reference dose (cRfD) if the "endpoint of toxicity" is not cancer. An "endpoint of toxicity" is simply the effect that the pesticide may cause (e.g., cancer, liver damage). OPP assumes that all non-cancer endpoints have a threshold, which means that an effect will not occur until a certain dose is reached. For cancer, toxicity may be expressed either as a potency factor (q_1*), when the cancer response is assumed to be linear, or as a Margin of Exposure (MOE), when the cancer response is believed to be non-linear. Exposure is generally expressed in milligrams of pesticide per kilogram of body weight per day of exposure (i.e., mg/kg/day). When comparing toxicity to exposure, which is done using the equations discussed in the risk assessment sections below, the risk assessor must "match" the duration of exposure (are people being exposed for a short term or long term?) with the toxicity (acute or chronic).

Under the requirements of FQPA, EPA is required to aggregate exposure and cumulate risk. What this means is that in assessing dietary exposure, all routes of exposure – both from the diet (food and drinking water), and from exposure in and around the home – must be considered. Prior to FQPA, only the exposure from food was considered in dietary exposure assessment; exposures in and around the home from dermal and inhalation routes were not aggregated with exposure from food. Cumulative risk means that in evaluating the dietary risk posed by the use of a pesticide, the risk from other chemicals with "common mechanisms of toxicity" must be considered. In the risk assessment discussion provided below, the calculations for aggregate exposure and cumulative risk are not discussed as they are still under development.

1. Toxicity Assessment

a. Non-Cancer Effects – *Reference Dose*. For non-cancer effects, toxicity is represented by a reference dose; it may be calculated for acute effects (aRfD) and chronic effects (cRfD). RfDs are calculated by determining the No-Observed-Adverse-Effect Level (NOAEL) from either acute or chronic toxicity studies (the choice of study depends on which type of RfD is being calculated – aRfD or cRfD) and dividing it by the appropriate uncertainty factors. Typically, a 10-fold factor is applied to account for variation within the human population (i.e., intraspecies); and an additional 10-fold factor is applied to account for the differences between humans and animals as the animal data are translated to humans (interspecies).

If the RfD will be used in dietary risk assessment, then it is adjusted to take into account the FQPA Safety Factor for infants and children. Such an adjusted reference dose is called a Population Adjusted Dose (PAD). Like the RfD, it may be acute (aPAD) or chronic (cPAD). In making the decision regarding the FQPA Safety Factor, the Agency takes into account both information on the toxicity of the pesticide and the completeness of the toxicity and exposure databases. For more information on how the Agency applies the FQPA Factor, see the draft document "Standard Operating Procedures for the HED FQPA Safety Factor Committee," November 6, 1998. ***[Future hotlink]***

b. Cancer Effects

Linear Effect - *Cancer Potency Factor (q_1*)*. The cancer potency factor, which is commonly known as a q_1*, is the relative strength of a carcinogen. The bigger the q_1*, the more potent the carcinogen. It is calculated using a sophisticated computer model that assumes linearity at low doses.

Non-Linear Effect - *Margin of Exposure*. For some carcinogenic pesticides, it is not considered appropriate to calculate a potency factor. In these cases, the cancer effect is assumed to have a threshold, as for non-cancer effects, and as such, a Margin of Exposure (MOE) is derived. The MOE is a ratio, calculated by dividing the toxicity Point of Departure (such as a NOAEL) by the estimated or calculated exposure level.

2. Dietary Risk Assessment. Risk is a function of toxicity and exposure. The equation that is used for dietary risk assessment depends on the nature of the toxicity: Non-Cancer (acute or chronic) or Cancer (non-threshold or threshold). The basic equations used in calculating dietary risk are listed below. No equation is listed for cancer, non-linear.

In reviewing these equations, please keep in mind that the actual dietary risk calculations are quite intensive and are done using a sophisticated computer software program called DEEM™ (Dietary Exposure Evaluation Model), which is a product of Novigen Sciences, Inc. The software contains food consumption data from the USDA Continuing Survey of Food Intake by Individuals (CSFII) conducted 1989-1992 and 1994 and 1996 (2 survey data sets). DEEM™ compares user-incorporated pesticide residue data on foods to the reported consumption of those foods and calculates a dietary exposure value in mg/kg/day as well as a 'risk' value. DEEM™ is both a deterministic, point estimate, and probabilistic, distributional, exposure and risk assessment tool.

a. Basic Equations for Dietary Risk Assessment

Non-cancer, acute: $\%aPAD = \frac{DietaryExposure(mg/kg/day)}{aPAD} x 100$

Non-cancer, chronic: $\%cPAD = \frac{DietaryExposure(mg/kg/day)}{cPAD} x 100$

Cancer, linear: Cancer Risk = Dietary Exposure x q_1*

b. Assessing Dietary Exposure from Food. Estimates of exposure to pesticides in food are derived from two distinct pieces of information: the amount of pesticide residue that is present in and on food (i.e., the residue level) and the types and amounts of food that people eat (i.e., food consumption). The residue information comes from the numerous crop field trials, monitoring data, and other sources where the amount of pesticide residues on a given commodity is measured. Consumption information comes primarily from USDA surveys of what people eat. Other information that OPP uses, but not always directly in the calculation, are the use-related data of site and typical agricultural practices (application rate, frequency, PHI).

OPP typically performs a food exposure assessment for two different exposure time frames – short-term or "acute" exposures and long-term or "chronic" exposures; each assessment is calculated differently. In chronic exposure assessment, the risk assessor is attempting to estimate a person's average food exposure over the long term (e.g., several years to a lifetime). Consequently, the use of average (or mean) residue value for each food commodity, the average (or mean) consumption of food commodities, and the average percent of crop treated is generally regarded as appropriate (estimates of exposure through drinking water are subsequently combined with these estimates of exposure through food to calculate combined exposure through food and water). In an acute food exposure assessment, however, the risk assessor is trying to estimate the range of exposures that individuals could encounter on a single day and determine the exposure to which "high-end" persons could be subjected (where "high-end" is defined as a plausible estimate of exposure for those individuals at the upper-end of the exposure distribution). Consequently, the use of high-end residue values, high-end consumption, and high-end percent of crop treated is regarded as appropriate.

EPA has long used a “tiered-approach” to assess acute and chronic food exposure. That is, the Agency performs its initial food exposure assessment using “worst-case” assumptions – that tolerance-level pesticide residues are present on 100% of each crop for which its use is approved. Such residues are often referred to as “farm-gate” residues because sampling occurs before the crop has entered the channels-of-trade and has had a chance to “lose” any of its pesticides residues. These farm-gate residues are considered worst-case because in the field tests the pesticide is applied at the label’s maximum application rate using the maximum number of applications (frequency) and the minimum pre-harvest interval. If the acute and/or chronic risks do not meet the applicable safety standard based on these worst-case residue levels, EPA then will "refine" them by incorporating "real-world" information (as appropriate), such as %CT; residue information obtained from food monitoring programs or surveys such as market basket data, PDP data, and FDA monitoring data; and information on consumer practices such as washing and peeling. In refining the worst-case residue levels, EPA uses BEAD’s “maximum” percent of crop treated, which is known as the probabilistic maximum, for acute assessments. For chronic assessments, the Agency uses BEAD’s “typical” percent of crop treated, which is a weighted average.

For more information on the specifics of how the Agency conducts food exposure and risk assessments, see the draft paper "A User's Guide to Available EPA Information on Assessing Dietary (Food) Exposure to Pesticides," ***[Future hotlink]*** December 22, 1998.

3. Residential Exposure. The term "residential exposure" applies to non-occupational pesticide use in and around the home, as well as in areas such as schools, parks, daycare centers, and other institutional settings. The exposure can occur while the pesticide is being applied (i.e., application exposure) or after the pesticide has been applied (i.e., post-application exposure). An example of residential application exposure is a homeowner treating his lawn, and an example of residential post-application exposure is a child playing on the recently treated lawn. Both application and post-application exposures can occur over a short term, an intermediate term, or a long term. Most exposure (both application and post-application) to pesticides that are used in and around the home will be of a short- to intermediate-term duration; there are relatively few instances of long-term residential exposure.

As with dietary, the equation that is used for residential risk assessment depends on the nature of the toxicity – Non-Cancer (short-term, intermediate-term, or long-term) or Cancer (linear or non-linear). The basic equations used in calculating residential risk are listed below. As with dietary, no equation is listed for the cancer, linear.

a. Basic Equations for Residential Risk Assessment

Non-cancer, short-term:

$$\text{MOE} = \frac{\text{NOAEL}}{\text{Residential Exposure}}$$

Non-cancer, intermediate-term:

$$\text{MOE} = \frac{\text{NOAEL}}{\text{Residential Exposure}}$$

*Cancer, non-threshold: Cancer Risk = Residential Exposure x q_1**

NOTE:
These equations apply to exposures that occur during application, and during post-application.

b. Assessing Residential Exposure. Addressing residential exposures to the general population, and particularly to children, is a complex task. Because data for the level of pesticide residues in residential settings are not usually available (studies are "conditionally required" which means that they are required only when certain toxicity and/or exposure criteria have been met), the Agency relies primarily on modeling data and assumptions as the basis for its residential exposure estimates. The draft "Standard Operating Procedures for Residential Exposure Assessments," December 19, 1997, provides guidance to this end. This document is commonly referred to as the "Residential SOP's."

Application Exposure

To calculate residential application exposure (short-term, intermediate-term, and long-term), the following equation is used:

Residential Application Exposure = (Unit Exposure) × (Application Rate, Frequency) × (Area Treated)

Information on calculating the unit exposure can be found in the Residential SOP's. For short- and intermediate-term assessments, the application rate and frequency are taken from the label. For long-term assessments, typical information is needed; this is not always available. Assumptions are generally used for area treated.

Post-Application Exposure

To calculate residential post-application exposure (short-term, intermediate-term, and long-term), the following equation is used:

Residential Post-Application Exposure = (Transfer Coefficient) × (Amount of Pesticide Residue) × (Duration of Exposure)

A transfer coefficient is a number that represents how much pesticide gets transferred from the object that has pesticide in or on it (e.g., lawn, carpet, a treated plant) to a person. It is derived using the Residential SOP's. For short-term residential exposure assessments, the amount of pesticide residue is calculated by using information on product formulation and application rates from the pesticide label. However, for intermediate- and long-term assessments, typical use information is needed; it is not always available. Duration of exposure is another parameter where information is lacking.

For additional information on residential and worker assessment, see the draft paper "Framework for Assessing Non-Occupational, Non-Dietary (Residential) Exposure to Pesticides," December 22, 1998. ***[Future hotlink]***

4. Occupational Exposure. Occupational exposure refers to exposure that occurs to professional workers who mix, load, and apply pesticides and to those who work in fields, orchards, or other treated areas after the pesticide has been applied. Like residential exposure, occupational exposure occurs during application (e.g., a farm worker using a pesticide on a field of crops) and during post-application activities (e.g., scouting the fields, harvesting the crops). Both application and post-application exposures can occur over a short term, an intermediate term, or a long term.

The basic equations used to calculate occupational risk are essentially the same as for residential exposure (except for differences in the exposure calculation, as seen earlier). They are listed below.

a. Basic Equations for Occupational Risk Assessment

Non-cancer, short-term: $MOE = \frac{NOAEL}{Occupational\ Exposure}$

Non-cancer, intermediate-term: $MOE = \frac{NOAEL}{Occupational\ Exposure}$

Non-cancer, long-term: $MOE = \frac{NOAEL}{Occupational\ Exposure}$

Cancer, linear: Cancer Risk = Occupational Exposure x q_1*

b. Assessing Occupational Exposure. Like residential exposure, occupational exposure data are conditionally required. Over the years, the Agency has developed the Pesticide Handlers Exposure Database (PHED), which provides surrogate data that are used in estimating occupational exposure. PHED is a generic database containing voluntarily submitted empirical exposure data for workers mixing, loading, or applying pesticides. It currently contains data for over 2000 monitored exposure events. The basic assumption underlying the system is that exposure to pesticide handlers can be calculated generically, based on the available empirical data for chemicals, as worker exposure is primarily a function of the formulation type and the handling activities (e.g., packaging type, mixing/loading/application method, and clothing scenario), rather than chemical-specific properties.

Application Exposure

To calculate occupational application exposure (short-term, intermediate-term, and long-term), the following equation is used:

Occupational Application Exposure = (Unit Exposure) × (Application Rate) × (Frequency) × (Area Treated per Day)

The Unit Exposure is generally derived from PHED. For short- and intermediate-term occupational exposure assessments, the application rate and frequency are derived from the pesticide label. For long-term assessments, the typical application rate and frequency are used. The area treated means how many acres (in the case of agricultural crops) are expected to be treated by an individual in one day. For short- and intermediate-term assessments, EPA generally uses the maximum application rate, frequency, and area treated, while for long-term assessments, typical areas are used.

Post-Application Exposure

To calculate occupational post-application exposure (short-term, intermediate-term, and long-term), the following equation is used:

Occupational Post-Application Exposure = (Transfer Coefficient) × (Amount of Pesticide Residues) × (Duration of Exposure)

The transfer coefficient is derived from human monitoring studies involving workers engaged in post-application field activities, along with measurements of the amount of pesticide residues on the foliage of the crops with which the workers are involved. Short- and intermediate-term occupational exposure assessments are calculated by using information on product formulation and maximum application rates from the pesticide label. However, for long-term assessments, typical use information is needed; it is not always available. Duration of exposure is another parameter where information is lacking.

B. Where Use-Related Data Are Used in Risk Assessment

1. Making the Decisions Regarding the FQPA Safety Factor. In making the decision on the FQPA Safety Factor for infants and children, EPA uses use-related information, semi-quantitatively. That is, in making this decision, the Agency needs to know, among other things, the likelihood that infants and children will come in contact with the pesticide under investigation and to have some general idea of the magnitude of exposure. The information is not included in the calculation, *per se*. Specifically, the following use-related information is used:

Extent of Use

Site. Where is the pesticide used? On food crops? As a lawn treatment? In industrial settings (e.g., as an antimicrobial in drilling fluid)? What is the likelihood that infants and children would be exposed?

2. Assessing Exposure and Risk from Food

To assess dietary exposure to pesticides, which includes the tiering process, EPA needs the following use-related information:

Extent of Use

Site. Which food crops is the pesticide used on? Before any food exposure assessment can be done, reviewers need to know what foods may contain pesticide residues.

% CT. Percent crop treated is an important component of the tiering process. As noted earlier, OPP develops more refined estimates of exposure to pesticides through food when its initial, "worst-case" assessment does not meet the applicable safety standard. These higher tier exposure assessments use %CT information to estimate what portion of the residue sample data listed as "no detects" should be considered as zero, because the crop was not treated with the pesticide. As explained in a draft science policy paper (Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments; 11/30/98 ***[Future hotlink]***), samples which are reported as "non-detects" and which are presumed to have been treated, are assigned a default value, typically equal to ½ the level of detection (LOD).

Typical Use Practices for Agricultural Products

Application Rate, Frequency, and PHI. Typical application rates, frequencies, and PHI's have long been used qualitatively in dietary risk assessments, particularly for the higher tier chronic assessments. For example, residue monitoring data reflect typical application rates, frequencies, and PHI's. Also, when the registrants have submitted residue decline studies, typical use rates have been used to characterize the data.

In the past OPP has not routinely used typical application rates, frequencies, and PHI's in risk assessments, quantitatively, because it has not has the appropriate residue data for estimating how changes in rates, etc. would affect residues in food. An OPP science policy paper describes the types of data that can be used to refine residue estimates, outlines the basic characteristics of useful data, discusses how residue data and usage data are linked, and explains how EPA will use these types of data in its dietary exposure assessments (Data for Refining Anticipated Residue Estimates Used in Dietary Risk Assessments for Organophosphate Pesticides; Draft 3/26/99). ***[Future hotlink]***

3. Assessing Residential Exposure

Much of the use-related information needed to calculate residential exposure is not routinely collected; these data needs are mentioned below. Routinely collected use-related information that are used in residential exposure estimates are:

Extent of Use

<u>Site</u>. Where exactly is the pesticide used? On the lawn? In cracks and crevices?

<u>Formulation</u>. Different formulations have different exposure potentials. For example, if the pesticide is placed inside an enclosed container (e.g., a bait trap) instead of being sprayed, the potential exposure to people and wildlife will be much lower. In addition, knowing the particle size is important when the formulation is granular.

Data Needs. In terms of being able to determine the amount of pesticide applied and the duration of exposure, the only data routinely available are those from the pesticide label. This is generally adequate for acute exposure assessment; however, for chronic exposure, information on how the pesticide is actually used (typical application rates), how often (frequency), and for how long (duration of exposure) is needed.

4. Assessing Occupational Exposure

Use-related information is used for occupational exposure assessment. Specifically,

Extent of Use

<u>Site</u>. On which type of crops is the pesticide used? Low growing crops such as tomatoes? Tree crops?

<u>Formulation</u>. Different formulations yield different levels of exposure. For instance, a pesticide that is packaged for use in a water-soluble bag will result in much less exposure to the worker than a pesticide that is formulated as a powder.

Typical Use Practices for Agricultural Products

<u>Application Rate and Frequency</u>. As taken from the label, these parameters provide information on maximum and minimum values that are needed for short- and intermediate-term exposures.

<u>Method of Application</u>. The application method can have a significant impact on the level of exposure for pesticide mixers, loaders, and applicators. For example, a worker would receive far less exposure applying a pesticide using an enclosed cab than with an open cab tractor.

Data Needs. Information that is not ordinarily available to OPP but which would be extremely useful in assessing occupational exposure, is the amount of a pesticide that a typical individual applies per day, for how many days out of the year along with the timing and exact nature of reentry activities (e.g., scouting).

C. Summary Table of Use-Related Information and Risk Assessment

The following table provides a summary of where use-related information is utilized in human health risk assessments. "Types of Use Information" is described in section II.A of this paper.

Table 2. Where Use-Related Information Is Used in Human Health Risk Assessment

Types of Use Information		Aspect of Risk Assessment			
		FQPA Safety Factor	Food Exposure	Residential Exposure	Occupational Exposure
Extent of Use	Site	✔	✔	✔	✔
	% CT		✔		
	Total pounds a.i.				
	Formulation			✔	✔
Typical Use Practices for Agri-cultural Products	Application Rate		✔	✐*	✐
	Frequency		✔	✐	✐
	PHI		✔		✔
	Method of Application			✐	✔

*"✐" Currently, these highly-desirable parameters are generally unavailable.

V . The Role of Use-Related Data in Drinking Water and Ecological Risk Assessments and Environmental Risk Characterizations

The kinds of pesticide use-related information which risk assessors use in developing risk assessments for dietary (food) and residential exposure are equally important to those who develop drinking water and ecological risk assessments and environmental risk characterizations. This section describes how different types of use-related information (Table 3) are used in the following assessments:

1. interpretation and design of monitoring studies and mathematical models that can be used to estimate human exposure to pesticide concentrations in drinking water, and

2. interpretation of monitoring data for fish and wildlife kills and estimation of fish and wildlife exposure to pesticides in the environment.

A. Drinking Water Assessments

Estimating Pesticide Concentrations. One of the first steps in assessing risk is to estimate how much of a pesticide could be in a stream or body of water after it rains and some portion of the pesticide is washed into the water. Knowing which pesticides and how much of these pesticides will be applied during a particular period of time to outdoor sites, such as farm fields and power line rights-of-way, is critical in developing a risk assessment. EPA needs this information to determine whether fish or other aquatic species in the stream will be exposed to enough of the pesticide to cause them to become sick or to die. Similarly, risk assessors need to know how much of a pesticide is applied on sites surrounding a reservoir in order to estimate potential drinking water concentrations.

Currently, EPA uses a tiered approach involving a combination of models and monitoring data to estimate pesticide concentrations in drinking water (EPA's Science Policy 5: Estimating the Drinking Water Component of a Dietary Exposure Assessment, (access through the Internet **http://www.epa.gov/oppfead1/trac/science/**) December 1998; FR Notice 1/4/99, p. 162). In Tier I, EPA uses screening models (GENEEC and SCI-GROW) to provide conservative estimates of pesticide concentrations in surface and ground waters. For these mathematical screening models, the Agency uses the maximum pesticide application rates and number of applications indicated on the label. If the screening model estimates from Tier I exceed the drinking water level of comparison (DWLOC), then the Agency can use more refined screening models (Tier II), such as PRZM/EXAMS, to estimate drinking water concentrations. In contrast to Tier I models, Tier II models use more realistic, site-specific use scenarios, such as typical or average rates of application rather than maximum rates. High quality information concerning what pesticides are typically used on individual crops, what percentage of a watershed is typically cropped, and when and how the pesticides are used is critical in developing accurate and realistic estimates of pesticide levels in water.

The Agency can also use monitoring data (Tier III), when available and reliable, to prepare a quantitative risk assessment, but reliable monitoring data are often not available on pesticide levels in drinking water, particularly drinking water derived from surface water systems. This means that for most pesticides, EPA must use mathematical formulas and equations, combined with pesticide label use information (i.e., maximum application rates and number of applications, and minimum interval between applications, along with any label-based use restrictions) and pesticide-specific data on the fate and transport properties of the pesticides to develop screening level estimates of pesticide concentrations in vulnerable surface water and ground water.

Targeting Monitoring Efforts. Another important use of pesticide use-related information is in targeting environmental monitoring efforts. EPA works closely with the United States Geological Survey (USGS) and other Federal and State agencies in designing drinking water studies and in deciding where to collect water samples for analysis. Monitoring pesticide concentrations in streams, lakes, or reservoirs is very costly, and pesticide concentrations in water can vary depending on the usage of the pesticide, with the highest concentrations usually occurring immediately after application. In designing a monitoring study to determine the national distribution of the highest annual concentrations of an acutely toxic pesticide, it is more cost-effective to target sampling to treated areas shortly after the pesticide has been used, rather than sample all community water systems, or even a random sample of systems.

Interpreting Monitoring Data. If drinking water monitoring data are not accompanied by information on pesticide use in the monitored areas, it is difficult to interpret the data. What does a large number of drinking water measurements reported as "non-detects" in one region or area really mean when several reported values in another region are many times higher? What does it mean when measured values range over several orders of magnitude? These questions can only be answered if pesticide use data in the watershed or basin are available and can be used in interpreting the data.

In general, EPA does not have adequate monitoring data to predict accurately the distribution of pesticide levels in drinking water on a national or regional basis. However, when drinking water monitoring data are available, EPA must analyze the data and decide how it fits specific assessment endpoints that are addressed in the risk assessment. Many times monitoring studies have been designed and/or data have been collected in a manner that limits their usefulness for estimating the distribution of drinking water concentrations in areas of use. More often than not, reported values from water monitoring studies vary within a region and across regions by several orders of magnitude. Without specific historical information on the use of the pesticide in the sampled area, it is difficult to understand the reasons for these differences. In many cases, the number of samples in which pesticides are detected greatly exceed the number which contain measurable residues. However, these monitoring results can be influenced by many factors, such as the pesticide use, the physiochemical properties of the pesticide, and the analytical sensitivity of the methods. Because EPA often does not have adequate use data to correlate "non-detects" with the actual use areas, it is difficult to conclude that a pesticide will not, in fact, reach water at measurable levels.

How Use-Related Data Can Improve Drinking Water Models. EPA has a continuing need to develop improved, cost-effective mathematical models that will help risk assessors accurately predict pesticide concentrations in the environment. Once the Agency develops or modifies a model, it needs to determine whether the change results in an improved capability to predict exposure levels. The Agency demonstrates this by "validating" the model, that is by comparing environmental measurements under actual use conditions with model-predicted levels of exposure. Accurate data on application methods, timing of application, and quantities and types of pesticides which are applied in a watershed along with quality water monitoring data from that same watershed are key ingredients in the development and validation of improved models for producing accurate estimates of pesticide concentrations in water. With the development of cost-effective, well-validated models, collection of actual environmental monitoring data will become less important.

B. Ecological Risk Assessments and Risk Characterizations

Ecological Risk Assessment. Assessment of ecological risk from the use of a pesticide can be defined as estimating the likelihood or probability that adverse effects (e.g., mortality to single species or organisms, or reductions in populations of non-target organisms, or disruption in community and ecosystem level functions) will occur, are occurring, or have occurred. This assessment consists of two activities: characterization of environmental exposure and characterization of ecological effects. Ecological effects data can come from a variety of sources, such as documented fish or bird kills, field and laboratory tests, and chemical structure-activity relationships. In characterizing the ecological effects from the use of a pesticide, risk assessors analyze the data and quantify the relationship between the pesticide and the assessment endpoint (i.e., LC_{50} for fish or birds).

Characterizing environmental exposure involves an estimation of the amount of pesticide residue that will be in the environment and available to non-target organisms as well as a characterization of the non-target organisms (i.e., numbers, types, distribution, abundance) which will be in contact with these residues. In completing exposure assessments for ecological risk assessment purposes, EPA estimates residues that might occur in/on vegetation, seed, and insects; in soil; in surface water; in groundwater and in sediment. Use-related information is essential for such exposure estimates. EPA uses pesticide labeling information on the maximum application rate, frequency, method of application, sites of application, and timing of application in the development of exposure estimates. These exposure estimates are then used in combination with ecological effects information to develop ecological Risk Quotients (RQs), which are then used in the assessment and characterization of the ecological risk posed from the use of a pesticide. The RQ is calculated by dividing the estimated exposure of the pesticide by its potential ecological effects. The higher the RQ, the greater the risk to the environment (Urban and Cook, 1986 Standard Evaluation Procedure [SEP] for Ecological Risk Assessment, EPA-540/9-85-001).

Initial screening level ecological exposure assessments assume maximum application rates and maximum frequency of application and minimum intervals between applications. If the screening assessment yields a significant risk, the Agency may refine its assessments based on more typical or average use rates and frequencies which are included in the Quantitative Usage Analysis. With better use information, EPA can develop more accurate estimates of risks posed by pesticides to non-target fish, plants, and wildlife.

Environmental Risk Characterization. Pesticide use information is also vital in the environmental risk characterization process, the final phase of risk assessment. During this phase, the likelihood of adverse effects occurring as a result of exposure to a pesticide is evaluated. Risk characterization consists of risk estimation and risk description. In risk estimation, the exposure estimation and the ecological effects characterization are compared along with estimating and summarizing the associated uncertainties. Risk description summarizes the results of the risk estimation and uncertainty analysis and assesses confidence in the risk estimates through a discussion of the weight-of-evidence. The second element involves interpretation of ecological significance, which describes the magnitude of the identified risks to the assessment endpoint.

Often the quantitative ecological risk assessment (i.e., development of Risk Quotients) is not enough to effectively capture the potential ecological impacts associated with the use of a pesticide. In the risk characterization, scientists expand the risk assessments by making more detailed regional assessments and use additional use-related information (i.e., total acres planted and percent crop treated) to make a qualitative assessment of the ecological risk. Other use-related information, such as the most likely time of the year that a particular pesticide will be applied is important in determining whether certain habitats will be affected, such as the nesting area for a particular species of waterfowl relative to the nesting period.

Table 3. Types of Use-Related Information Used in Risk Assessment

Type of Use-Related Information	Aspect of Risk Assessment		
	Drinking Water Assessment	Ecological Assessment	Environmental Characterization
Which Pesticide	✓	✓	✓
Site	✓	✓	✓
Application Rate	✓	✓	✓
Frequency	✓	✓	✓
Application Method	✓	✓	✓
Interval Between Applications	✓	✓	✓
When Applied			✓
% CT			✓
Total Acres Planted			✓

VI. Role of Use-Related Information in Risk Management Decisions

Use-related information plays a vital, even critical role in EPA's formulation of risk management decisions for pesticides in registration, reregistration, tolerance reassessment, and Special Review. The availability or lack of use-related information can significantly influence the outcome of EPA's regulatory decisions about pesticides under review, especially if pesticides pose significant risks.

A. Registration

Under FIFRA, a pesticide product cannot be sold or used in the U.S. until it is registered by EPA. In conducting pre-market registration reviews, the Agency considers a full complement of data submitted by the manufacturer or registrant, demonstrating the pesticide's human health and environmental effects. EPA registers those pesticide products that can be used according to label directions and precautions without posing unreasonable risks to people or the environment. All pesticide products with food uses must also meet the safety standard and other provisions of FFDCA, as amended by FQPA.

Public Interest Finding. Before approving the conditional registration of a pesticide containing a new active ingredient (that is, to grant a time-limited registration based on less than the full complement of usually-required data), EPA must conclude that the pesticide's use is in the public interest. In other words, the Agency must find that the new pesticide fulfills a need that is not being met or is less risky than other alternatives, or that the benefits of the new pesticide exceed those of existing alternatives. To make this public interest finding, EPA considers use-related information including what pesticides are already registered, how they are used, and how efficacious they are in controlling the target pest.

Section 18 Emergency Exemptions. Under section 18 of FIFRA, EPA may exempt State or Federal agencies from any provision of the Act, including provisions which regulate the manner in which a pesticide is made available for use or is used, if emergency conditions exist which require an exemption. EPA thus may grant requests from the States for temporary, unregistered pesticide uses if emergency conditions exist and sufficient data are available to determine that the limited use under an emergency exemption would be safe. A pest control "emergency" is a situation in which no registered pesticide is available to control the target pest; no economically or environmentally feasible alternative practice is available; and the pest outbreak is new, presents significant risks to human health, threatened or endangered species, beneficial organisms, or the environment, or will cause significant economic loss. In deciding whether a pest control need constitutes an emergency, EPA considers use-related information. For example, the Agency determines whether any alternative pesticides or pest control practices are available, their effectiveness, and their costs.

Minor Use Registrations. EPA must give pesticide minor uses special consideration in making many registration-related decisions. The FQPA defines a minor use as either a crop which is grown on less than 300,000 acres (as determined by USDA) or a use which does not provide sufficient economic incentive to support the initial or continuing registration of a pesticide for that use. To qualify as a minor use under the economic definition, the use must also meet one of the following four criteria:

- there are insufficient efficacious alternative registered pesticides available for the use; or
- the alternatives to the pesticide use pose greater risks to the environment or human health; or
- the minor use pesticide plays or will play a significant part in managing pest resistance; or
- the minor use pesticide plays or will play a significant part in an integrated pest management program.

In addition, public health pesticide uses are a special class of minor uses under FQPA. FQPA defines a public health pesticide as one used to control a disease vector or other recognized health protection use in a public health program. EPA must consult HHS for a determination on whether it is of significant benefit in a public health program before the Agency can cancel, suspend or take other significant regulatory action against a public health pesticide use.

Use-related data are required to determine whether a pesticide meets the criteria under the economic definition of a minor use or a public health pesticide. Information from minor use pesticide users, such as growers or public health pest control program coordinators, regarding their pest control practices and priority needs is critical for the Agency to accurately prioritize registration of the pesticides required to provide pest management for minor uses.

B. Reregistration, Tolerance Reassessment, and Special Review

The purpose of EPA's pesticide reregistration and tolerance reassessment programs is to reassess, characterize, and if necessary, reduce the risks posed by use of pesticides that are already on the market. The goal is to ensure that these pesticides meet present-day safety standards and fully protect the health of infants, children, and other sensitive groups within the U.S. population.

The Special Review process has served for many years as a forum for formal, in-depth analysis and weighing of both the risks and benefits of pesticides that appear to pose unacceptable hazards to human health or the environment. Use-related information is employed in many ways as the Agency reassesses pesticide risks and reaches risk management decisions through these three interrelated programs.

FQPA's New Safety Standard. During the past 10 years, EPA has been reviewing older pesticides under FIFRA to make sure that they meet current scientific and regulatory standards and do not pose unreasonable risks. This reregistration program was made more stringent by the 1996 FQPA. The new law directs EPA, in regulating pesticides used in or on food crops, to apply a more rigorous safety standard – "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," including all anticipated dietary, drinking water, residential, and other non-occupational exposures. Within 10 years, EPA must reassess all existing tolerances to ensure that they meet this new safety standard. FQPA establishes time frames for tolerance reassessment and directs EPA to complete one third of the overall task approximately every three years. The Agency expects to meet the first FQPA goal and complete its reassessment of the first one third of all existing tolerances by August 3, 1999.

In reassessing tolerances – and in making reregistration decisions and resolving pending Special Reviews – EPA must consider the potentially riskiest pesticides first, and

- consider aggregate exposure of the public to a pesticide residue from all sources, including food, drinking water, and residential uses;
- consider the cumulative effects of pesticides that share a "common mechanism of toxicity";
- consider special sensitivities of infants and children; and
- consider possible endocrine disruptor effects.

In conducting the reregistration, tolerance reassessment, and Special Review programs, EPA's approach has changed fundamentally from balancing pesticide risks vs. benefits under FIFRA, to assessing aggregate exposure and cumulative effects in order to reduce overall risks, thus meeting the safety standard of FQPA. Under FQPA, the Agency's emphasis now is generally on evaluating, characterizing, and managing pesticide risks, rather than on assessing benefits. However, when overall levels of acceptable risk are exceeded, EPA needs thorough, good quality use-related information in order to compare, prioritize, and make informed choices among uses to effectively manage risks. Under the new provisions of FQPA, then, pesticide use information is vital to EPA in reaching reasonable, informed, workable regulatory decisions.

Mitigating and Managing Risks. If some uses of a registered pesticide are found to pose serious human health or ecological risks, EPA explores ways to mitigate or manage the risks by modifying the problematic uses. Use-related information is vital to EPA in developing practical, workable risk mitigation proposals and risk management decisions. Timely, reliable, verifiable, real-world use information helps risk managers understand the range of risk mitigation options available – to determine which options are viable and which are not – and to anticipate the impacts of various courses of action. For example, it is possible that because of concerns about spray drift into important aquatic habitat, the ecological risk assessor may suggest prohibiting aerial application. Having available information on whether the pesticide can practically be applied by ground spray in an effective manner is critical to the risk manager in understanding whether this mitigation measure is viable.

The various techniques to mitigate pesticide risks largely involve changes in the way a pesticide is used; mitigation measures are geared to the type of pesticide exposure and health or environmental risk posed. Note that in all the exposure scenarios below, deleting or canceling pesticide uses is also an option, to be employed if no other risk reduction solutions are viable.

- **To reduce dietary exposure and risk**, options include reducing the amount or frequency of pesticide applications; adjusting the timing of applications; lengthening pre-harvest intervals; including rotational crop restrictions; adding or increasing plant-back intervals.

- **To reduce residential exposure and risk**, options include classifying the product as a Restricted Use Pesticide, which limits use only to trained individuals who have been certified as competent to apply the pesticide safely; adding label language to prohibit household use; requiring no-treatment buffer zones around residential areas; limiting the amount, frequency or timing of applications in households or residential areas; adding user safety requirements and recommendations to product labels; improving use directions, precautions, and first aid information on product labels.

- **To reduce worker exposure and risk**, options include classifying the product as a Restricted Use Pesticide; requiring the use of personal protective equipment (PPE); lengthening restricted entry intervals (REIs); requiring “double” notification of workers (warning workers of pesticide applications in two ways – orally and by posting signs); requiring use of engineering controls such as closed application systems or special packaging; adding technology requirements to minimize spills during mixing/loading; prohibiting certain methods of application; adding user safety requirements and recommendations to product labels; improving use directions, precautions, and first aid information on product labels.

- **To reduce ecological exposure and risk**, options include limiting the amount, frequency, or timing of applications; imposing geographical limits on applications; requiring buffer zones or vegetative buffer strips to protect sensitive areas; requiring Spray Drift Advisory language on labeling; requiring various Environmental Hazard statements on product labels.

- **To reduce ground water or surface water exposure and risk**, options include requiring Ground Water, Surface Water, and/or Spray Drift Advisory language on product labeling; requiring mixing/loading setbacks from wells, rivers and lakes; requiring buffer zones between treated sites and drinking water sources or bodies of water; prohibiting use in areas overlying karst geology.

This spectrum of risk mitigation options is narrowed and focused to address the unique situation of each pesticide by factoring in information on the pesticide’s current, real-world uses. The availability of good quality, use-related information enables the Agency’s risk managers to craft workable solutions to mitigate risks during reregistration, tolerance reassessment, and Special Review.

In situations where pesticide risks are serious and risk mitigation options include severe use restrictions or cancellation, real-world knowledge about pesticide uses and alternatives becomes critical. Such information provides risk managers flexibility and supports more informed, reasonable, and protective decisions. FQPA prohibits human dietary risk from pesticide residues in food inconsistent with its safety standard. When a pesticide's overall level of acceptable risk (represented by the Reference Dose, or RfD) is exceeded and modifying its uses will not be sufficient, then EPA must consider deleting or canceling some uses in order to reduce exposure and lower the risk. Up-to-date, real world information about the pesticide's current uses and alternatives is extremely valuable to the Agency in deciding which uses to retain and modify and which to cancel, to most effectively reduce risks while minimizing negative impacts on agriculture and food production. Similarly, in making decisions about groups of pesticides that share common mechanisms of toxicity, pesticide use-related information will help indicate which pesticide/crop combinations in the group are the least essential from an economic standpoint. EPA is committed to an open, inclusive process in deciding which pesticide uses to retain and which to cancel or restrict during reregistration, tolerance reassessment, and Special Review.

In certain limited situations, EPA may continue to make pesticide risk management decisions under FIFRA. That statute prohibits the continued registration of any pesticide that causes unreasonable adverse effects – that is, any unreasonable risk to people or the environment taking into account the economic, social, and environmental costs and benefits of its use. This balancing of pesticide risks and benefits can result in cancellation of high risk pesticide uses unless a compelling argument for the pesticide's benefits can be made, usually based on use-related information. If reliable, real-world use information indicates that there are no alternatives to a risky pesticide use, then the Agency may be willing to retain the use in its final decision. If, on the other hand, use information indicates that viable alternatives are available, EPA is more likely to propose that the use be discontinued or canceled.

The Special Review process traditionally has included a full, formal benefits analysis that is equal in depth and significance to the analysis of risks. Sophisticated, detailed use-related information is essential to this process, especially since the outcome of a Special Review can range from returning uses to registration, to use restrictions, to – in the worst case – cancellation of some or all uses. During a Special Review, EPA conducts a comprehensive risk/benefit analysis of each use of the pesticide. Potential risks are evaluated by considering factors such as adverse effects to health or the environment, the magnitude of exposure of humans and other non-target organisms, and the size of the population at risk. Benefits of use are evaluated by assessing the availability, efficacy, cost and risks of alternative pest control methods, as well as the impact on users, consumers, and other parties (except the registrant) if the pesticide were canceled. High quality, use-related information is vital to this assessment.

Special Review consists of a series of clearly defined steps or phases, through which EPA seeks to achieve the goal of reducing a pesticide's risks while fully considering its benefits. In recent years, many Special Reviews have been resolved through negotiated settlements. In such proceedings, pesticide registrants reach an agreement with the Agency to modify the terms and conditions of their registrations in order to reduce risks to an acceptable level. The modifications may include canceling uses, changing use patterns, changing application methods or rates, or imposing protective measures. In negotiating Special Review agreements, EPA relies on timely, high quality, use-related information to formulate effective, workable risk reduction measures. Use-related information enables EPA's risk managers to understand the impacts of various options, and make choices among uses if some must be canceled to reduce overall risk.

VII. What Next?

This paper has provided a road map of the types of pesticide use-related data OPP uses in pesticide risk assessment and risk management, where these data come from, and how the Agency employs these data. Use-related data cover the extent of pesticide use across different sites and geographic regions, typical use patterns, use profiles for specific pesticides, and the role of pesticides in pest management systems. Data are collected in a variety of ways and come from a variety of sources. OPP scientists also invest substantial resources to organize, summarize, and evaluate use-related data. These data are used in a number of risk assessment and risk mitigation activities related to dietary and drinking water exposure, residential and occupational exposure, and environmental exposure. Ultimately, the Agency bases its registration or reregistration decisions on risk assessments and mitigation plans that rely on detailed and accurate use-related data.

At the same time, however, OPP is fully aware that there is room for improving the scope of its use-related data and the methods used to analyze them, and is taking some concrete steps to facilitate improvement in these areas. To enhance its collection of use-related data in agricultural sites, OPP has been working more closely with USDA-NASS, California DPR, registrants, grower groups, and other stakeholders. Agency scientists are continuing to work with organizations that provide use-related data to refine statistics – particularly data on the distribution of application rates and pre-harvest intervals – to provide the most accurate real-world data for risk assessment and risk management. Risk assessors are striving to use real-world data in refined risk assessments, and risk managers are using these data to find opportunities to mitigate risk as efficiently as possible. As risk assessments are refined, quantitative and qualitative usage analyses are being refined as well to make sure the data are as current as possible. In these ways and more, OPP is refining the basis for regulatory actions and increasing the transparency with which these actions are taken.

Even with these steps, there are still several areas where OPP's use-related data are limited and could benefit from increasing stakeholder participation to fill these data gaps. There are also areas where the Agency would like to solicit comments from EPA stakeholders on ways to improve EPA methods for collecting, evaluating, and employing use-related data.

A. Limitations of EPA Use-Related Data

Although EPA has a wide range of sources for use-related data, there are some fundamental limitations to the Agency's data. In some cases data limitations arise from differences between data that have been historically collected and new data needs that have arisen as a result of implementing FQPA. In other cases, the limitations arise from persistent gaps in the available pesticide use data. Data limitations fall into three general categories: sites covered, location specificity, and patterns of observed data (distributions of observations).

In spite of efforts to find use-related data for all important sources of exposure, EPA still lacks data for important sites in important locations, both in agricultural and non-agricultural settings. NASS has been collecting pesticide use data in agriculture since 1967, but due to many factors (including budget limitations and competing priorities), these data have not been collected on a regular basis. Since 1990, NASS has surveyed the major field crops (corn, soybeans, wheat, and cotton) for the major producing states, and conducted fruit and vegetable surveys in alternate years for many major fruit and vegetable crops. These surveys cover states that grow 80-85% of each crop studied and approximately 50-65% of total acres for all crops grown within the continental United States. While NASS has good quality data, coverage is limited for many minor crops, livestock and poultry uses, seed treatments, post-harvest use, transportation and storage of agricultural products, and other niche agricultural uses. In some cases – livestock uses, seed treatment, and post-harvest use for example – data available to EPA are extremely limited.

Compared to agriculture, the universe of non-agricultural pesticide use data is still quite sparse. As mentioned throughout this paper, data on pesticide use in non-agricultural sites – both residential and commercial – are important for refining risk assessments and management plans in the drinking water, environmental, and public health areas. The section on human dietary and residential risk assessment (Section IV) describes how the lack of use-related data on residential uses, worker exposure sites, and sites resulting in exposure to infants and children influences risk assessments. The section on drinking water and ecological risk assessments (Section V) details how missing data on important non-agricultural sites like rights-of-way and other watershed components can increase the difficulty of generating risk assessments. Because pesticides are used on such a wide range of non-agricultural sites, EPA would greatly benefit from increased coordination among its stakeholders to find ways to collect and provide the Agency with use-data in these sites.

Location or geographic referencing is another important aspect of pesticide use data where EPA needs to strengthen its efforts. Some risk assessments for human health are based on aggregating data into several different regions, each comprising a group of states. EPA will need to work with its sources of data, particularly in non-agricultural sites, to obtain data that can be summarized regionally. Additionally, as noted earlier, watershed-specific use-related data are crucial for refined drinking water and ecological risk assessments, and linking pesticide use to water quality monitoring. Geographic referencing is a system where geographic location can be specified in detail, and such referencing is becoming more common in databases. While EPA's main sources of data do not geo-reference their use-related data, it is possible to do so once confidentiality concerns for specific survey respondents have been addressed. In addition, it may also be possible to geo-reference historical data with commercial computer programs that have recently become available. Incorporating location-specific parameters with use data will require a substantial effort, but should greatly improve risk assessments when these data become available.

In addition to location specificity, some refinements require other key parameters associated with use data. Frequency distributions of pre-harvest intervals and application rates across groups of farmers in agricultural sites will greatly aid in implementing the probabilistic tools used in refined risk assessments. Because such data are not always easy to collect, EPA has been – and will need to continue – working with NASS, registrants, grower groups, trade organizations, proprietary data sources, and scientists in public universities to collect and extract this key information from the data they provide.

B. EPA Invites Comments

As part of its effort to improve the quality of its regulatory actions through public participation, EPA invites comments in several areas related to pesticide use-related data. The following paragraphs discuss issues from each of the main sections (use-related information, human health risk assessment, drinking water and ecological risk assessment, and risk management decisions) where comments from outside the Agency may assist in refining the way EPA regulates pesticides.

To improve its use-related data, EPA seeks comments in several specific areas:

1. What can EPA do to improve the quality of its use-related data? [Because improving data reliability appears to entail greater costs, the Agency would benefit from strategies to expand its use-related data, while maintaining reliability at the least cost.]

2. What could be done to expand the scope of EPA's use-related data?

3. Given some notable gaps in the Agency's data, for which use sites does EPA most urgently need to acquire use-related data?

4. What existing data bases, particularly for non-agricultural sites, are accessible for use by the Agency? [Expanding coverage of non-agricultural use sites is a priority, and identifying available data bases is going to be an important part of this process.]

5. What quantitative methods or modifications should EPA consider in making its estimates of likely maxima for pesticide use?

Several aspects of human health risk assessment data needs could also benefit from views from outside EPA:

6. In cases where residue data are not readily available, what data should the Agency use in human health risk assessments? [This is particularly important for residential or commercial use sites where data are scarce.]

Since residue data are not always available, how much data might be needed to validate residue reduction studies that link actual pesticide use to residues that pose dietary risks?

7. When different types of use-data are available for different sites and from different sources, how can these be incorporated into risk assessments?

8. What methods of data aggregation are most appropriate where regional analysis involves combining data from different geographic regions?

9. For which aspects of human health risk assessment is it appropriate to use typical or average use estimates, in contrast to estimates of likely maxima or allowable label rates?

Similar issues arise in ecological and drinking water risk assessments. Model validation, specifically, is an area where EPA invites public comment:

10. What methods are most effective for calibrating and validating models of pesticide risk in watersheds? [As described earlier in this paper, the limited availability of real-world data requires that some risk assessments be done based on simulation models

of the systems involved. The agency could use public input on ways of improving methods for linking pesticide use to residue levels in drinking water supplies.]

11. To what degree does use-related information need to align with EFED model scenarios, particularly when model scenarios involve a high degree of geographic specificity.

Lastly, there are several areas where the registration and reregistration process would benefit from increased stakeholder involvement:

12. How can EPA improve the development and use of economic models to predict impacts on different economic sectors – agricultural sectors in particular – to anticipate the economic consequences of its regulatory actions?

13. How can EPA refine models that estimate the micro-impacts (on individual users or groups of users) of regulatory actions that change the pattern and expense of pest control? (In order to do this, EPA will require an expansion of its data base detailing the efficacy of chemical and non-chemical methods of pest control.)

In fulfilling its mandates to regulate pesticides in the U.S., EPA directs a broad effort to collect, organize, evaluate, and employ a wide range of use-related data. After several decades of conducting these efforts under different legislative and executive climates, EPA has developed a coordinated system of analytical and decision making tools that rely on these data. At the same time, this system is continuing to evolve, especially as FQPA implementation continues apace. The Agency has invested significant resources in developing the tools and procedures needed to implement FQPA, but also recognizes that there are areas where improved data and methods can play an important role. With the participation of its stakeholders, EPA is committed to continue its efforts at improving the scope, quality, and transparency of use-related data used in pesticide risk assessment and management.

Attachments: Appendices A, B, and C

USE PROFILE REPORT
(FOR ILLUSTRATION ONLY)

Report Run Date: 12/07/98

A. Chemical Overview

Chemical Name:	S,S,S-Tributyl phosphorotrithioate
Case No:	2145
Chemical Code:	074801
CAS No.:	78-48-8
Trade Names:	Def 6, Folex 6EC, tribufos, tribuphos.

Multiple active ingredient products contain: None

B. Use Profile

Type of Pesticide: Defoliant

Mode of Action: It is an organophosphorus (OP) compound.

Use Sites:
- Terrestrial food crop
  - Cotton (unspecified)
- Terrestrial food+feed crop
  - Cotton
  - Cotton (unspecified)

Target Pests:
Undefined CONSISTING OF: no pest
Weeds: not applicable; desired effect: defoliant

Formulation Types Registered: Emulsifiable concentrate, Form not identified/liquid

Methods and Rates of Application:

Equipment - Aircraft; Ground

Method - Foliar treatment; Spray; Ultra low volume

Rates - See LUIS Report (Appendix A)

Timing - Foliar; Preharvest

Use Practice Limitations: None

THIS IS A QUA FOR A FICTITIOUS CHEMICAL FOR ILLUSTRATION ONLY

Quantitative Usage Analysis for SampleChem

Case Number: 0999 PC Code: 99999

Based on available pesticide survey usage information for the years 1987 through 1995, an annual estimate of SampleChem's total domestic usage averaged approximately 4,200,000 pounds active ingredient (a.i.) for 5,300,000 acres treated. Most of the acreage is treated with one pound a.i. or less per application with usually only one application per year. SampleChem is a fungicide with its largest markets, in terms of total pounds active ingredient, allocated to corn (50%), sorghum (21%), alfalfa (8.4%), and rice (6.5%). Crops with a high percentage of the total U.S. planted acres treated include artichokes (40%), broccoli (21%), rice (9%), and cauliflower (8%). Usage has been shifting from liquid formulations to wettable powder formulations.

Fred B. Analyst, 555-1111, 06/01/99

APPENDIX B

SampleChem AI #:9999 EPA's QUALITATIVE USAGE ANALYSIS Analyst: Fred B. Analyst 555-1111 06-01-99

Usage Site	Acres) (000) Grown	Acres Treated (000) Weighted Average	Acres Treated (000) Est Max	% of Crop Treated Weighted Average	% of Crop Treated Est Max	Lb AI Applied (000) Weighted Average	Lb AI Applied (000) Est Max	Average Application Rates lb ai/ acre/yr	Average Application Rates # appl /year	Average Application Rates lb ai/A /appl	States of Most (% of total lb ai used on this site)
Cranberries	29	0	2	1%	7%	0	2	1.1	1.0	1.1	WA 100%
Strawberries	51	2	4	4%	8%	1	2	0.6	1.0	0.6	OR WA 85%
Apples	452	16	42	3%	9%	45	125	2.8	1.6	1.8	WA OR 97%
Broccoli	71	15	23	21%	32%	13	24	0.9	1.0	0.9	MI DE OH NC WI 85%
Cabbage	84	3	4	3%	5%	4	7	1.4	1.4	1.1	VA NJ NC 89%
Cauliflower	34	3	5	8%	15%	4	9	1.6	1.0	1.6	NJ FL VA 94%
Pumpkins	41	2	6	4%	15%	2	6	1.2	1.0	1.2	NJ TX 97%
Watermelons	258	15	27	6%	10%	9	12	0.6	1.0	0.6	VA IN TX 88%
Potatoes	1,421	68	125	5%	9%	65	108	1.0	1.4	0.7	ND ID MN FL WA NC 66%
Sweet Corn	784	26	45	3%	6%	28	67	1.1	1.1	1.0	GA NY DE PA MD AL 70%
Artichokes	9	4	6	40%	59%	4	6	1.0	1.0	1.0	
Onions	149	4	9	2%	6%	4	11	1.2	1.4	0.8	NM NJ 82%
Corn	72,284	2,220	4,440	3%	6%	2,085	4,180	0.9	1.2	0.8	NE IL KS IA IN TX 53%
Barley	7,505	28	56	0%	1%	7	14	0.2	1.0	0.2	ND KY MT MN UT 82%
Oats/Rye	4,525	4	11	0%	0%	2	7	0.5	1.0	0.5	MS ND NH MI MT NC 84%
Sorghum	11,280	1,271	2,553	11%	23%	880	2,048	0.7	1.0	0.7	KS TX NE FL MO 83%
Rice	2,921	275	462	9%	16%	270	542	1.0	1.0	1.0	LA CA TX 87%
Wheat	66,652	121	263	0%	0%	37	85	0.3	1.0	0.3	VA AR 100%
Alfalfa	23,949	686	1,424	3%	6%	352	776	0.5	1.0	0.5	OK KS CA UT CO KY 49%
Peanuts	1,610	14	28	1%	2%	19	38	1.4	1.1	1.2	VA GA OK FL TX 84%
Canola	170								1.0		
Soybeans	62,879	61	121	0%	0%	40	79	0.7	1.1	0.6	DE IL MD ND NC KY 65%
Sunflower	2,745	75	211	3%	8%	36	121	0.5	1.0	0.5	ND KS SD 85%
Cotton	12,689	342	865	3%	7%	120	310	0.4	1.1	0.3	TX MS LA AR OK 85%
Flax	188	1	2	0%	1%	0	1	0.5	1.0	0.5	ND 100%
Sugar Beets	1,415	40	65	3%	5%	42	100	1.0	1.0	1.0	ID NE TX WY MT 82%
Sugarcane	852	16	32	2%	4%	20	40	1.3	1.0	1.3	FL LA 88%
Turf									1.0		
Tobacco	695	14	34	2%	5%	32	65	2.3	1.0	2.3	KY NC TN VA IN 84%
Bananas	-										
Coffee (Imported)	-										

Trees (Forest)		0					1.0		
Trees (Shade & Orn.)		0					1.0		
Woodland		0	1	0	0	0.3	1.0	0.3	GA FL 100%
Right of way				50	100				
Cooling Towers	-								
Ornamental Shrubs				3			1.0		
Total		5,324	8,094	4,176	6,531				

COLUMN HEADINGS

Weighted average--the most recent years and more reliable data are weighted more heavily.
Est Max = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1995.
Calculations of the above numbers may not appear to agree because they are displayed as rounded:
to the nearest 1000 for acres treated or lb. a.i.   (Therefore 0 = < 500)
to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

0* = Available EPA sources indicate that no usage is observed in the reported data for this site, which implies that there is little or no usage.
A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.
SOURCES: EPA data (1988-1997), USDA (1990-1996), and National Center for Food and Agricultural Policy (1992)

OP TOLERANCE REASSESSMENT USE/USAGE MATRIX
SAMPLE CROP SUMMARY – FOR ILLUSTRATION ONLY

Site: Apples	Overall Confidence Rating: High

Background: A total of 641,000 acres are planted in apples in the United states. Organophosphate pesticides (OP) represent 68% of all pesticide usage on this crop with an average of 2.82 applications per year. Analysis of OP usage was conducted for the following five major apple regions: New England (CT, MA, ME, RI, NH, NJ, NY, VT) , North Central (MI and OH), Appalachian-Southern (DE, GA, MD, NC, PA, SC, TN, VA, WV), Western (AZ and CA), and Pacific North. (OR and WA). Insecticide use patterns and key pests vary both between and within regions. In the absence of effective controls, key pests can destroy 50-90% of the crop. Due to low damage threshold levels in apples, biological control is limited to indirect pests (non-fruit feeding) with little contribution against direct pests.

Organophosphate	% Treated		# Applications		Rate (lb AI/A)		PHI (days)	
Pesticides	Max[23]	Avg[23]	Max[21]	Avg[2-11]	Max[21]	Avg[2-11]	Min[21]	Avg
azinphos-methyl	64.7	61.4	4	2.1	3.1	0.8	7	
chlorpyrifos	53	44	NS	1.6	4	1.4	30	
diazinon	6	3	NS	1.6	5	1.2	21	
dimethoate	14.9	7.4	NS	1.3	2.0	0.8	28	
malathion	15	10	NS	1.1	2.3	0.8	21	
methyl parathion	25	18	NS	1.0	2	2.0	21	
phosmet	34	22	NS	2.9	4	1.1	7	

Confidence Rating: H= high confidence = data from several confirming sources; confirmed by personal experience
M = medium confidence = data from only a few sources; may be some conflicting or unconfirmed info.
L = low confidence = data from only one unconfirmed source

Organophosphate Target Pests for Apple in New England Region (Primary pests controlled by the OP's)[6, 9, 17, 18]	
Major	Bug (Tarnished Plant), Aphids (Rosy Apple, Apple, and Spirea), Apple Maggot, Plum Curculio
Moderate	Leafroller (Obliquebanded and Redbanded))
Minor	Fruitworm (Green and Sparganothis), Sawfly (European Apple), Leafhopper (White Apple and Potato), Scale (San Jose), Mite (European Red), Leafminer (Spotted Tentiform)

Major = 20+% of all OP usage on pest; Moderate = 5-20% of all OP usage on pest; Minor =<5% of all OP usage on pest

Sources:

1. Proprietary EPA market share information.
2. U.S. Apple QUA+ - Washington. 1997.
3. U.S. Apple QUA+ - Virginia, West Virginia. 1997.
4. U.S. Apple QUA+ - Georgia, North Carolina, South Carolina and Tennessee. 1997.
5. U.S. Apple QUA+ - Pennsylvania. 1997.
6. U.S. Apple QUA+ - New England. 1997.
7. U.S. Apple QUA+ - Michigan. 1997.
8. U.S. Apple QUA+ - California. 1997.
9. QUA+ - New England Fruit Consultants.
10. QUA+ Michigan Apple Commission. 1997
11. QUA+ - Northwest Horticultural Council. 1997.

12. Orchard Pest Management; A Resource Book for the Pacific Northwest.1993. Good Fruit Grower, Yakima, WA.
13. Pacific Northwest 1998 Insect Control Handbook. 1998. Oregon State University.
14. 1997 Spray Bulletin for Commercial Tree Fruit Growers. Virginia, West Virginia and Maryland Cooperative Extension.
15. Pennsylvania Tree Fruit Production Guide. 1996-1997. College of Agricultural Science, Penn State University.
16. 1997 Fruit Spraying Calendar for Commercial Fruit Growers. 1997. Bulletin E-154. Michigan State University Extension.
17. Pest Management Recommendations for Commercial Tree Fruit Production. 1997. Cornell University.
18. 1996-1997 New England Apple Pest Management Guide. Cooperative Extension (Universities of Conn., NH, Maine, Rhode Island, Massachusetts and Vermont)
19. Apple Pest Management Guidelines. 1996. UCPMG Publication 12. IPM Education and Publications, U of CA, Davis.
20. Integrated Pest Management for Apples and Pears. 1991. Publication 3340. University of California.
21. Label Use Information System (LUIS) Version 5.0, EPA.
22. The All-Crop, Quick Reference Insect Control Guide (1997), Meister Publishing Company
23. EPA Crop Profile QUA.

APPENDIX C

OP TOLERANCE REASSESSMENT USE/USAGE MATRIX
SAMPLE PEST SUMMARY – FOR ILLUSTRATION ONLY

Site: Apple
Region: New England (Including: CT, MA, ME, RI, NH, NJ, NY, VT)

Pest[2, 3, 4, 5, 8]	Organophosphate[1, 2, 3, 4, 5, 8]	Efficacy[4, 5]	Mkt[1]	Class	Alt. Pesticide List[1, 2, 3, 4, 5, 8]	Efficacy[4, 5]	Mkt[1]	Constraints of Alternatives[2, 3, 8]
Timing: Pre-Bloom								
Tarnished Plant Bug (Major)	azinphos-methyl	●	High	Ca	carbaryl	●	---	**Permethrin** would harm aphid and mite predators and cause explosion in mite populations. Continued use of permethrin would lead to resistance bug populations.
	chlorpyrifos	●	Lo	Ca	methomyl	●	---	
	dimethoate	❍ - ☺	Lo	Ca	oxamyl	●	---	
	malathion	●	---	P	esfenvalerate	☺	Med	
	methyl parathion	●	---	P	permethrin	☺	High	
	phosmet	●	Lo	CH	endosulfan	❍	Lo	
Aphid (Rosy Apple) (Major)	azinphos-methyl	●	Med	Ca	carbaryl	●	---	Alternatives as good or better than chlorpyrifos for Rosy Apple Aphid but not other species. **Permethrin** would harm aphid and mite predators and cause explosion in mite populations. Continued permethrin use would lead to pest resistance.
	chlorpyrifos	❍ - ☺	High	Ca	methomyl	● - ❍	Lo	
	diazinon	● - ❍	---	Ca	oxamyl	❍	Lo	
	dimethoate	❍	Lo	P	esfenvalerate	❍ - ☺	Med	
	malathion	● - ❍	---	P	permethrin	❍ - ☺	Lo	
	methyl parathion	●	---	CH	endosulfan	❍ - ☺	High	
	phosmet	●	Lo	O	imidacloprid	● - ☺	---	

Pest Importance: Major = 20+% of all OP usage on pest; Moderate = 5-20% of all OP usage on pest; Minor = <5% of all OP usage on pest
Efficacy Rating: Excellent = ☺ Good = ❍ Fair = ● --- = Not rated for efficacy in state recommendations.
Market Share: High = 20+% OP of all usage on pest; Med = 5-20% of all usage on pest; Lo = <5% of all usage on pest, --- = not available for 1994-96.
Insecticides: C = Carbamates; P = Pyrethroids; CH = Chlorinated Hydrocarbons; IGR = Insect Growth Regulators; B = Biological; O = Other pesticides

APPENDIX C

OP TOLERANCE REASSESSMENT USE/USAGE MATRIX
SAMPLE PEST SUMMARY – FOR ILLUSTRATION ONLY

Site: Apple

Region: New England (Including: CT, MA, ME, RI, NH, NJ, NY, VT)

Pest[2, 3, 4, 5, 8]	Organophosphate[1, 2, 3, 4, 5, 8]	Efficacy[4, 5]	Mkt[1]	Class	Alt. Pesticide List[1, 2, 3, 4, 5, 8]	Efficacy[4, 5]	Mkt[1]	Constraints of Alternatives[2, 3, 8]
Timing: Pre-Bloom								
Leafroller (Oblique-banded and Red-banded) (Moderate)	azinphos-methyl	● - ☺	Med	Ca	carbaryl	●	---	Permethrin would harm aphid and mite predators and cause explosion in mite populations. Continued use would lead to resistant populations.
	chlorpyrifos	☺	Med	Ca	methomyl	☺	High	
	malathion	● - ❍	Lo	P	esfenvalerate	❍ - ☺	Med	
	methyl parathion	☺	---	P	permethrin	❍ - ☺	Med	
	phosmet	● - ☺	Med	CH	endosulfan	❍	Lo	
				B	Bacillus thuringiensis	☺	---	
Scale (San Jose) (Minor)	azinphos-methyl	---	Lo	CH	endosulfan	---	Lo	**Crop oil** is only Moderately effective against San Jose Scale.
	chlorpyrifos	---	High	O	petroleum oil	---	High	
	phosmet		High					

ADDITIONAL INFORMATION:
Apple production in the New England Region (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont) accounts for 17.9% of total acreage and 12.7 % of production for the US. OP usage represents 37% of all pesticide usage during the Pre-Bloom period in the New England Region.

SOURCES:
1. Proprietary EPA market share information.
2. U.S. Apple QUA+ - New England. 1997.
3. New England Fruit Consultants.
4. Pest Management Recommendations for Commercial Tree Fruit Production.. 1997. Cornell University.
5. 1996-1997 New England Apple Pest Management Guide. Cooperative Extension (Univ. of Connecticut, New Hampshire, Maine, Rhode Island, Massachusetts and Vermont)
6. The All-Crop, Quick Reference Insect Control Guide (1997), Meister Publishing Company.
7. Label Use Information System (LUIS) Version 5.0, EPA.
8. Communications with New England Extension Personnel and Apple Producers.

Pest Importance: Major = 20+% of all OP usage on pest; Moderate = 5-20% of all OP usage on pest; Minor = <5% of all OP usage on pest
Efficacy Rating: Excellent = ☺ Good = ❍ Fair = ● --- = Not rated for efficacy in state recommendations.
Market Share: High = 20+% OP of all usage on pest; Med = 5-20% of all usage on pest; Lo = <5% of all usage on pest, --- = not available for 1994-96.
Insecticides: C = Carbamates; P = Pyrethroids; CH = Chlorinated Hydrocarbons; IGR = Insect Growth Regulators; B = Biological; O = Other pesticides